

Urgent Field Safety Notice

CHC17-04.A.OUS

February 2017

ADVIA® Chemistry Systems

ADVIA Chemistry Aspartate Aminotransferase (AST) and Aspartate Aminotransferase concentrated (AST_c) Positive Bias after calibration with ADVIA Chemistry Enzyme 2 Calibrator lots 6JD079 and 6MD042

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

Table 1. Affected Product(s)

Assay	Test Code	Reference Number	Siemens Material Number (SMN)	Lot Number	Manufacturing /1st Distribution Date
ADVIA Chemistry Enzyme 2 Calibrator	ENZ 2 CAL	10916058	10916058	6JD079	2016-09-09/ 2016-11-08
				6MD042	2017-01-30/ 2017-02-09

Reason for Correction

Siemens Healthcare Diagnostics has confirmed a positive bias of up to 41% in quality control and patient results for Aspartate Aminotransferase (AST) and Aspartate Aminotransferase concentrated (AST_c) assays following calibration with ADVIA Chemistry Enzyme 2 Calibrator lots 6JD079 and 6MD042. Only Aspartate Aminotransferase (AST) and Aspartate Aminotransferase concentrated (AST_c) assays are affected. All other assays (ALT, ALT_c, ALTP5P, ALTP_c, ASTP5P and ASTP_c) using the ADVIA Chemistry Enzyme 2 Calibrator are not impacted.

Internal investigation has determined that quality control will detect this issue.

The issue with the ADVIA Chemistry Enzyme 2 Calibrator lots 6JD079 and 6MD042 is currently under investigation, no other lot of Enzyme 2 calibrator is available at this time. Siemens will provide an updated communication upon completion of the investigation.

Risk to Health

The risk to health due to this issue is negligible. AST would commonly be used in conjunction with other liver biomarkers, such as ALT. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

1. For customers who are in the process of converting from the fixed factor to the enzyme calibrated assay, the conversion to the calibrated Aspartate Aminotransferase (AST) and

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ADVIA Chemistry AST and AST_c after calibration with Enzyme 2 Calibrator lots 6JD079 and 6MD042

Aspartate Aminotransferase concentrated (AST_c) must be put on hold until the Siemens investigation into calibrator lots 6JD079 and 6MD042 is completed. Continue to use the fixed factor for all reagent lots of the ADVIA Chemistry AST and AST_c assay until the investigation into calibrator lots 6JD079 and 6MD042 is completed and Siemens provides further instructions.

2. Customers who have already converted from the fixed factor to the calibrated enzyme assay must switch back to the fixed factor AST and AST_c assay until the investigation into calibrator lots 6JD079 and 6MD042 is completed and Siemens provides further instructions. Please contact your local Siemens Technical Support Representative to schedule a Siemens visit to configure the software and to allow the conversion back to the fixed factor assay.
3. Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
4. Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.
5. Please review this letter with your Medical Director.

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.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Chemistry AST and AST_c after calibration with Enzyme 2 Calibrator lots 6JD079 and 6MD042.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC17-04.A.OUS dated February 2017 regarding ADVIA Chemistry AST and AST_c after calibration with Enzyme 2 Calibrator lots 6JD079 and 6MD042. 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.

1. 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:

Customer Sold To #:

Customer Ship To #:

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