



Urgent Field Safety Notice

11219826, Rev. A

January 2015

ADVIA® Chemistry Systems

ADVIA Chemistry Systems Drug Calibrator I Lot 3JD018 for Phenytoin 2 and Phenobarbital 2 Assays Calibrator Value Reassignments

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

Table 1. ADVIA Chemistry Systems Affected Product(s)

Product	Siemens Material Number (SMN)	Lot Number	Expiration
Drug Calibrator I	10376770	3JD018	April 2015

Reason for Correction

Siemens Healthcare Diagnostics has determined that incorrect calibrator lot values were assigned for ADVIA® Chemistry Systems Drug Calibrator I, lot 3JD018, for the ADVIA Chemistry Systems Phenytoin 2 (PHNY_2) and Phenobarbital 2 (PHNB_2) assays. This issue was determined to be the result of calibrator value miscalculation. Calibrator lot 3JD018 has now been value assigned to align with the correct calibrator values.

Internal investigation concluded that Quality Control results still recover within the manufacturer's ranges when using either the incorrect or corrected calibrator values.

NOTE: There is no change to the calibrator values for the ADVIA Chemistry Systems Theophylline 2 (THEO_2) assay.

Risk to Health

The differences in Phenytoin_2 and Phenobarbital_2 values observed when comparing the incorrect and corrected calibrator values would not impact the utility of these tests in clinical practice. The risk to health is negligible. Siemens is not recommending a review of previously generated laboratory results due to this issue.

Actions to be Taken by the Customer

- Refer to Table 2 in the Additional Information section for the new ADVIA Chemistry Drug Calibrator I, lot 3JD018 calibrator values for the ADVIA Chemistry Systems Phenytoin 2 (PHNY_2) and Phenobarbital 2 (PHNB_2) assays.
- Immediately after the update of the calibrator values on the ADVIA Chemistry system, recalibrate both assays.
- Please verify that your internal Quality Control results are within ranges established for your laboratory.

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- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

Please retain this letter with your laboratory records and with your ADVIA Chemistry Systems Drug Calibrator I kits, 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

Table 2. Calibrator Value Reassignments

ADVIA Chemistry Systems Phenytoin 2 Assay		
Lot 3JD018	Original Values	Revised Values
Cal Level 2	5.1 µg/mL [20 µmol/L]	4.5 µg/mL [17.82 µmol/L]
Cal Level 3	10.2 µg/mL [40.39 µmol/L]	8.6 µg/mL [34.06 µmol/L]
Cal Level 4	20.0 µg/mL [79.2 µmol/L]	17.9 µg/mL [70.88 µmol/L]
Cal Level 5	40.6 µg/mL [160.78 µmol/L]	36.0 µg/mL [142.56 µmol/L]
ADVIA Chemistry Systems Phenobarbital 2 Assay		
Lot 3JD018	Original Values	Revised Values
Cal Level 2	9.9 µg/mL [42.67 µmol/L]	10.5 µg/mL [45.26 µmol/L]
Cal Level 3	19.7 µg/mL [84.91 µmol/L]	20.3 µg/mL [87.49 µmol/L]
Cal Level 4	39.1 µg/mL [168.52 µmol/L]	40.2 µg/mL [173.26 µmol/L]
Cal Level 5	76.4 µg/mL [329.28 µmol/L]	79.0 µg/mL [340.49 µmol/L]

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Chemistry Systems Drug Calibrator I Lot 3JD018 for Phenytoin 2 and Phenobarbital 2 Assays Calibrator Value Reassignments

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 11219826, Rev. A dated January 2015 regarding ADVIA Chemistry Systems Drug Calibrator I Lot 3JD018 for Phenytoin 2 and Phenobarbital 2 Assays Calibrator Value Reassignments. 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.