SIEMENS

Urgent Field Safety Notice

10819261, Rev. B

August 2014

ADVIA® Chemistry Systems

A1c_3 Calibrator Bias

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

Table 1. ADVIA Chemistry Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
A1c_3	10491408	10491408	3HD044 3LD068

Reason for Recall

Siemens Healthcare Diagnostics is conducting a recall for the ADVIA® Chemistry Systems A1c_3 calibrator lots listed in Table 1. Siemens has confirmed that the ADVIA Chemistry Systems A1c_3 method may exhibit a percent bias of -9% to +11% for hemoglobin (Hb)A1c samples when using A1c_3 calibrator lots 3HD044 and 3LD068. Depending on quality control limits, this issue may not have been detected.

NOTE: The percent bias range is a percentage of the HbA1c result. It is NOT absolute HbA1c units.

The root cause is currently under investigation.

Risk to Health

The management of patients with hyperglycemia is dependent upon the monitoring of diet, lifestyle, glucose concentrations, HbA1c, and the adjustment of therapy to glycemic control. A percent bias of up to +11% may be considered clinically significant at clinically relevant HbA1c ranges between ~5.5% and 8.0%, and may result in the modification of the therapy for hyperglycemia. The modification of hyperglycemic therapy can increase the risk of occurrence of hypoglycemia, which may be observed through personal glucose monitoring and/or patient symptoms.

Siemens is not recommending a general look back for the laboratory for previously generated results when using these calibrator lots. Siemens is providing a physician letter with retesting guidance for physicians. See the attached physician letter.

P,.O. Box 6101
Newark, DE 19714
www.siemens.com/diagnostics

Actions to be Taken by the Customer

- Discontinue use of and discard the product(s) listed in Table 1.
- Please review this letter with your Medical Director.
- An informational physician letter is attached to this communication. Siemens recommends reviewing this letter with your Medical Director. The letter should be tailored (see highlighted and underlined text in the physician letter) to your laboratory and used for clinicians who have ordered HbA1c testing in your laboratory between the date when your laboratory began using the affected products in this recall and the date when your laboratory discontinued using the affected products in this recall.
- Please contact your local Siemens sales representative for assistance with determining appropriate HbA1c testing solutions for your laboratory.
- Complete and return the Urgent Field Safety Notice Effectiveness Check attached to this letter within 30 days.

Frequently Asked Questions

1. Are there any calibrator lots unaffected by this issue?

   A1c_3 calibrator lot 4DD071 will be available for shipment on August 15, 2014.

2. Can I continue to run this assay with A1c_3 calibrator lots 3HD044 and 3LD068, depending on what my quality control results are?

   No. Control material may not detect the bias. Control recovery could present as unaffected, unlike patient samples.

3. Will I be reimbursed for discarded product?

   Please contact your local Siemens sales representative for assistance with any reimbursement requests and to determine appropriate A1c testing solutions for your laboratory.

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.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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URGENT FIELD SAFETY NOTICE EFFECTIVENESS CHECK

A1c_3 Calibrator Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10819261, Rev. B dated August 2014 regarding A1c_3 Calibrator Bias. Please read each 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 ☐

2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes ☐ No ☐

   If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	**Quantity of Affected Product in inventory that has been discarded**	**Replacement Quantity Required**
A1c_3 Calibrator / 10491408 / 3HD044		
A1c_3 Calibrator / 10491408 / 3LD068		

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 (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

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[Laboratory Letterhead]

Informational Physician Letter

Date

Customer Contact Title
Customer Account Name
Customer Account Address

Subject: ADVIA® Chemistry Systems Hemoglobin A1c_3 Assay

Dear Customer Name,

Siemens Healthcare Diagnostics has confirmed through internal investigation that between date when your laboratory began using the affected products in this recall and date when your laboratory discontinued using the affected products in this recall, a percent bias of -9% to +11% may have been observed on HbA1c results around 6.0% HbA1c for your patient(s). This bias may not have been detected by the laboratory's internal quality control testing and patient results may have been reported to you.

We ask that you consider retesting HbA1c in cases where all of the following events have occurred:

1. You have had HbA1c testing performed on your patient(s) during the dates listed above,
2. You have made adjustments in therapy based solely on the HbA1c value(s), and
3. You have not had follow up HbA1c testing on your patient(s) after date when your laboratory discontinued using the affected products in this recall.

If these events occurred and you choose to repeat HbA1c testing, we will repeat this testing free of charge.

We apologize for the inconvenience this has caused you and your patient(s), and are here to answer any questions or concerns you may have.

Sincerely,

[Insert Laboratory Medical Director Info]