SIEMENS

Urgent Field Safety Notice

CHC-15-19.A.OUS

September 2015

ADVIA® Chemistry Systems

Hemoglobin A1c_3 (A1c_3 and A1c_3M) Reagent Lots
Positive Bias

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

Table 1. ADVIA Chemistry Systems Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Hemoglobin A1c_3 (160 test kit)	A1c_3, A1c_3M	10379673	10379673	230
Hemoglobin A1c (800 test kit)	A1c_3, A1c_3M	10485591	10485591	230
Hemoglobin A1c (800 test kit)	A1c_3, A1c_3M	10485591	10485591	231

Reason for Recall:

Siemens Healthcare Diagnostics has confirmed the Hemoglobin A1c_3/ A1c_3M reagent kit lots listed in Table 1 used on the ADVIA® 1200, 1650, 1800, 2400, and XPT Chemistry Systems may demonstrate an increased occurrence of high %HbA1c bias. Siemens internal investigation demonstrates reagent lots 230 and 231 may exhibit a positive bias averaging 0.6% HbA1c units, ranging from -0.1% to 1.1% HbA1c units. The bias was observed when comparing %HbA1c means to NGSP pooled patient target-value assigned samples ranging from approximately 5.5% to 8.0% HbA1c. The maximum bias was observed at higher %HbA1c concentrations. QC samples may exhibit a similar bias.

Siemens is currently investigating the root cause of this issue.

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.

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

Hemoglobin A1c_3 (A1c_3 and A1c_3M) Reagent Lots

Positive Bias

A positive %HbA1c bias as described may be considered clinically significant at clinically relevant HbA1c values, 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 laboratory look back for previously generated results when using these lots.

Actions to be taken by the Customer

- Discontinue use of and discard the kit lots listed in Table 1.
- Please review this letter with your Medical Director.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- 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.

Question and Answer:

Question: How can I communicate this issue to Healthcare providers?

Answer: Siemens suggests the following wording:

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, HbA1c values between 5.5% and 8.0% may have been approximately 0.6% HbA1c units higher than expected.

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.

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FIELD CORRECTION EFFECTIVENESS CHECK

Hemoglobin A1c_3 (A1c_3 and A1c_3M) Reagent Lots

Positive Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC-15-19.A.OUS, Rev. A dated September 2015 regarding Hemoglobin A1c_3 reagents kit lots listed in Table 1 above used on the ADVIA® 1200, 1650, 1800, 2400, and XPT Chemistry Systems may demonstrate an increased incidence of high 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 products 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/A1c_3M Catalog 10379673/ SMN 10379673/ Lot 230 (160 test kit)		
A1c_3/A1c_3M Catalog 10485591/ SMN 10485591/ Lot 230 (800 test kit)		
A1c_3/A1c_3M Catalog 10485591/ SMN 10485591/ Lot 231 (800 test kit)		

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

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Hemoglobin A1c_3 (A1c_3 and A1c_3M) Reagent Lots

Positive Bias

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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