

### ADVIA® Chemistry XPT Systems

#### Issue with IFCC Ratio Equation for the ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment Assay

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

**Table 1. Affected ADVIA Chemistry Products**

Product	Siemens Material Number (SMN)
ADVIA Chemistry XPT System	10723034

#### Reason for Correction

Siemens Healthcare Diagnostics has identified an issue with the ratio equation provided on the ADVIA® Chemistry XPT System Software Test Definition (TDef) Version 1.0 disks (SMN: 11127343 and 11222123). This issue affects only the ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment (A1c\_3) results when HbA1c values are reported in International Federation of Clinical Chemistry (IFCC) equivalent units (HbA1cR).

The ADVIA Chemistry XPT system allows customers to run ADVIA Chemistry Hemoglobin A1c using manual pretreatment or automatic pretreatment. The system also allows reporting in either NGSP units (HbA1c% = %) or IFCC units (HbA1cR = mmol/mol).

The ratio equation used to calculate ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment (A1c\_3) results in NGSP units is not affected.

The ratio equations used to calculate ADVIA Chemistry Hemoglobin A1c\_3 Manual Pretreatment (A1c\_3) results in both IFCC and NGSP units are not affected.

The ratio equation used to calculate ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment (A1c\_3) results in IFCC units contains an error. The error results in falsely depressed HbA1cR results. Available data indicates results may be depressed up to -62% (with an average of -18%).

This issue does not impact HbA1cR results on any other ADVIA Chemistry System.

#### Risk to Health

The ADVIA Chemistry Hemoglobin A1c\_3 assay is intended for monitoring long-term glycemic control of persons with diabetes. The management of patients with hyperglycemia is dependent upon several factors, including but not limited to, the monitoring of diet, lifestyle, glucose concentrations, HbA1c, and the adjustment of therapy to glycemic control.

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Falsely depressed results as described may be considered clinically significant at clinically relevant HbA1c values. The risk to health is limited to a potential misinterpretation of glycemic control or a delay in assessing long-term average hyperglycemia. When this issue occurs, the potential discordance between average glycemia and falsely depressed HbA1c values may be observed through personal glucose monitoring and/or patient symptoms.

Siemens is recommending a retesting of patient samples above 35 mmol/mol that have been generated within the previous 4 months. Please refer to the Instructions for Use (IFU) for specimen stability information.

Siemens recommends discussing the content of this letter with your laboratory director.

### **Actions to be taken by the Customer**

- If your laboratory is running the ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment (A1c\_3) assay on the ADVIA Chemistry XPT System and reporting results in IFCC units (mmol/mol), immediately discontinue reporting HbA1cR results. Contact your local Siemens Customer Care Center to schedule a service visit to correct the ratio equation on your system.
- Please review this letter with your Medical Director.
- All ADVIA Chemistry XPT customers must complete and return the Field Correction Effectiveness Check attached to this letter within 30 days. The faxback must be returned regardless of whether your account is running ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment (A1c\_3) assay.

Even if you are not running ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment (A1c\_3) assay on the ADVIA Chemistry XPT System, Siemens will contact you to replace the affected TDef disk.

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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### Question and Answer

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

**Answer:** Siemens suggests the following wording:

Siemens Healthcare Diagnostics has confirmed depressed results on the ADVIA Chemistry XPT System using the ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment assay for time period (date when your laboratory began using the affected products in this recall through the date your laboratory discontinued using the affected products in this recall). HbA1cR values may have been falsely depressed by up to -62% (with an average of -18%).

Please consider retesting HbA1cR in cases where all of the following events have occurred:

1. You have had HbA1cR testing performed on your patient(s) during the dates listed above,
2. You have made adjustments in therapy based solely on the HbA1cR value(s), and
3. You have not had follow-up HbA1cR testing on your patient(s) after (date when your laboratory discontinued using the affected products in this recall).

**Question:** Why is Siemens only recommending retesting samples above 35 mmol/mol?

**Answer:** Falsely depressed results less than or equal to 35mmol/mol would be clinically apparent in a diabetic patient.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHSW16-02.A.OUS dated July, 2016 regarding “*Issue with IFCC Ratio Equation for the ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment Assay*”. 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. Prior to receiving this Urgent Field Safety Notice my Laboratory was running the ADVIA Chemistry Hemoglobin A1c\_3 Automated Pretreatment (A1c\_3) assay and reporting in IFCC units on the ADVIA Chemistry XPT System. 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 (xxx) xxx-xxxx. If you have any questions, contact your local Siemens technical support representative.