SIEMENS Healthineers

Urgent Field Safety Notice

ACHC21-14.A.OUS.CHC

September 2021

ADVIA® 1800 Chemistry System
ADVIA® 2400 Chemistry System
ADVIA® Chemistry XPT

Falsely Depressed Enzymatic Hemoglobin A1c (A1c_E and A1c_EM) Results due to Reagent Carryover from the Urinary/Cerebrospinal Fluid Protein (UCFP) Assay

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

Table 1. ADVIA Chemistry Product

Assay	Test Code	Siemens Material Number (SMN)	Lot Number
ADVIA Chemistry Urinary/Cerebrospinal Fluid Protein	UCFP	11319151	All lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed the potential for ADVIA Chemistry Urinary/Cerebrospinal Fluid Protein reagent carryover impacting Enzymatic Hemoglobin A1c (A1c_E and A1c_EM) results. Falsely depressed Enzymatic Hemoglobin A1c results are observed when the assay is processed after the UCFP test on the ADVIA Chemistry systems (See tables 2-3). This issue can impact A1c_E/A1c_EM results for quality control (QC), patient samples, and calibrators. No other assays are impacted by UCFP carryover on the ADVIA Chemistry systems.

Investigation of this issue indicates that the addition of a Clean 1 wash using Probe Wash 1 is an effective mitigation in preventing UCFP reagent carryover.

The resolution of this issue will be implemented in AP Tool v1.11 and TDef v1.07 which will be available soon. In the interim, please follow the instructions in the “Additional Information” section below.

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Table 2. Impact of UCFP carryover on Hemoglobin A1c (%) Results

Sample	A1c_E result (%)	A1c_E result after UCFP (%)	% Bias
QC L1	4.48	4.18	-7%
Mixture of QC1/ QC2	7.14	5.62	-21%
Patient Sample	8.13	5.98	-26%

Table 3. Impact of UCFP carryover on Hemoglobin A1c (mmol/mol) Results

Sample	A1c_E result (mmol/mol)	A1c_E result after UCFP (mmol/mol)	% Bias
QC1	25.4	22.2	-13%
Mixture of QC1/ QC2	54.5	37.9	-30%
Patient Sample	65.3	41.8	-36%

Risk to Health

In scenarios where Hb A1c is run after UCFP, the potential exists for misinterpretation of Hb A1c levels, which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical history and symptomology as well as to additional laboratory testing such as blood glucose values and/or serial Hb A1c testing. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Perform the instructions provided in the “Additional Information.” Section.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

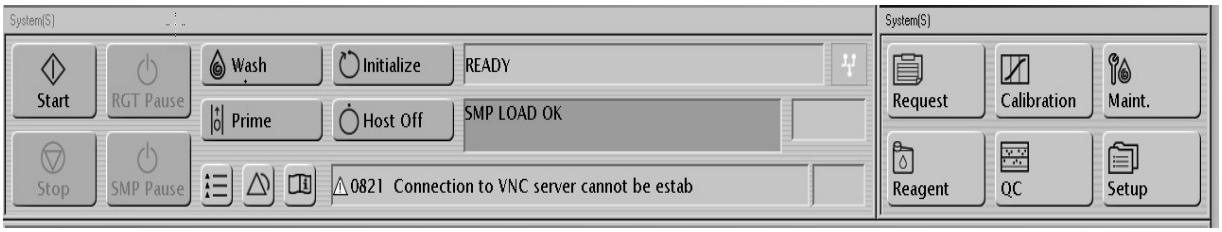
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative

Additional Information

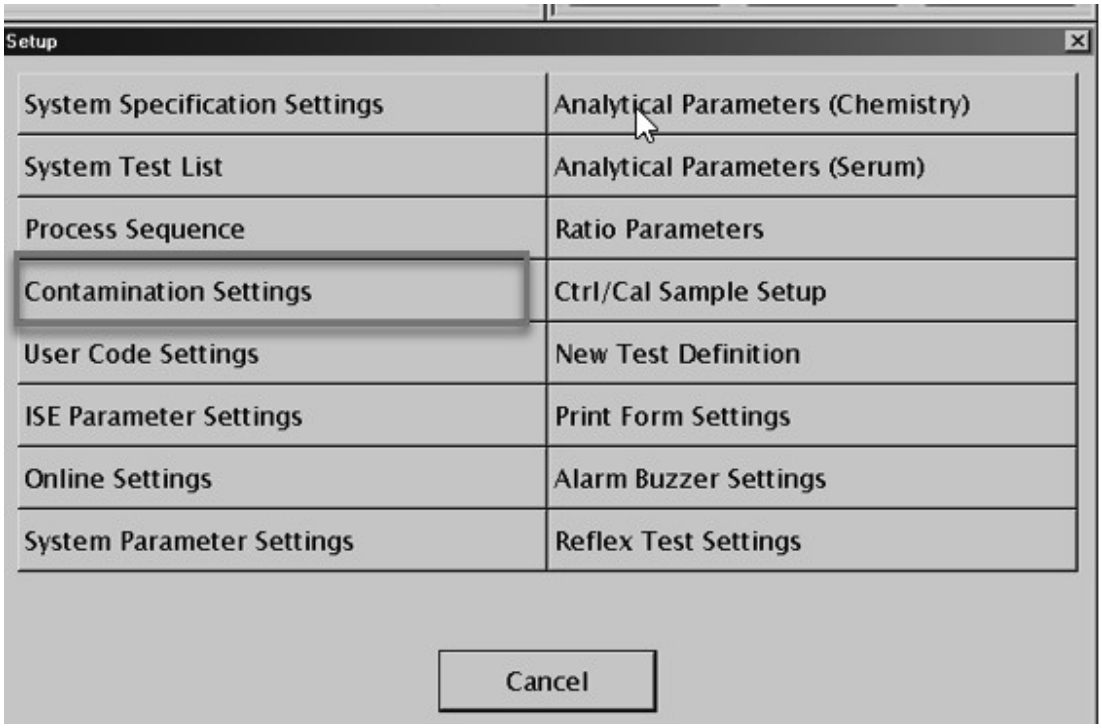
Please edit the settings as per the instructions below for the specific ADVIA Chemistry systems.

ADVIA 1800/2400 Chemistry System

1. Ensure system is in the Ready state.
2. Log on as tech_manager or Supervisor
3. Select **Setup** on the Menu Panel



4. Select **Contamination Settings**



5. Select the **Next Page** button until you come to the next available usable area. NOTE: Do not leave spaces or type over existing listings.
6. Add the Contamination Avoidance Settings
    a) Verify that the Set Type is:
    Setting Condition for avoiding reagent pipette contamination.
    b) Use the drop down and Select **RTT1** for pipette contaminated
    c) Enter the Systems Tests number for **UCFP (59)** in the Substance contaminating area
    d) Use the drop down and select **R1** for the Reagent Probe
    e) Enter the Systems Tests number for **A1c_E (6)** or **A1c_EM (19**) in the Substance contaminated area.
    f) Use the drop down and select **R1** for the Reagent Probe.
    g) Enter **999** for the Influence effect.
    h) Use the drop down and select **clean1** as the preventative detergent
    Note: Probe Wash 1 is the same as clean1

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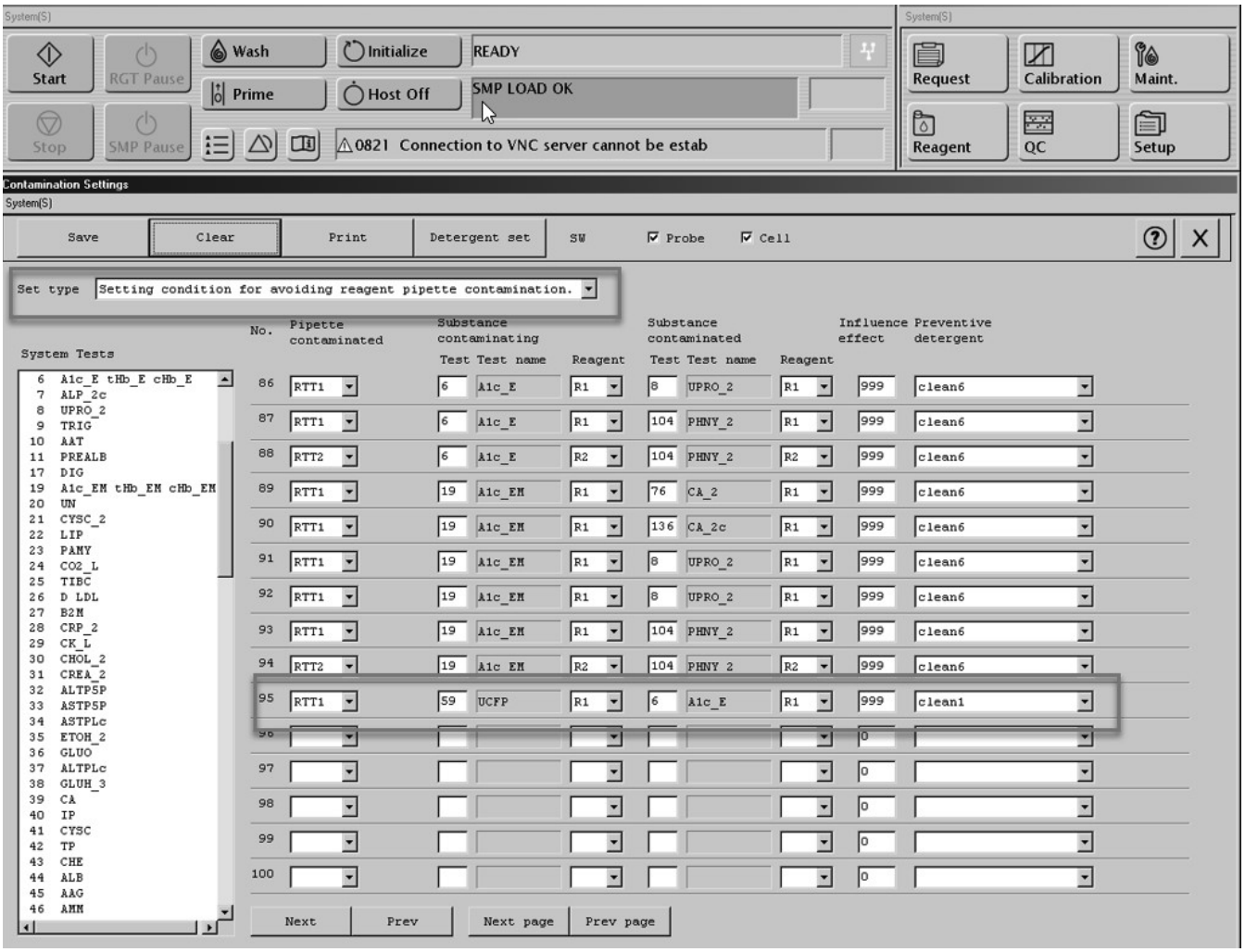

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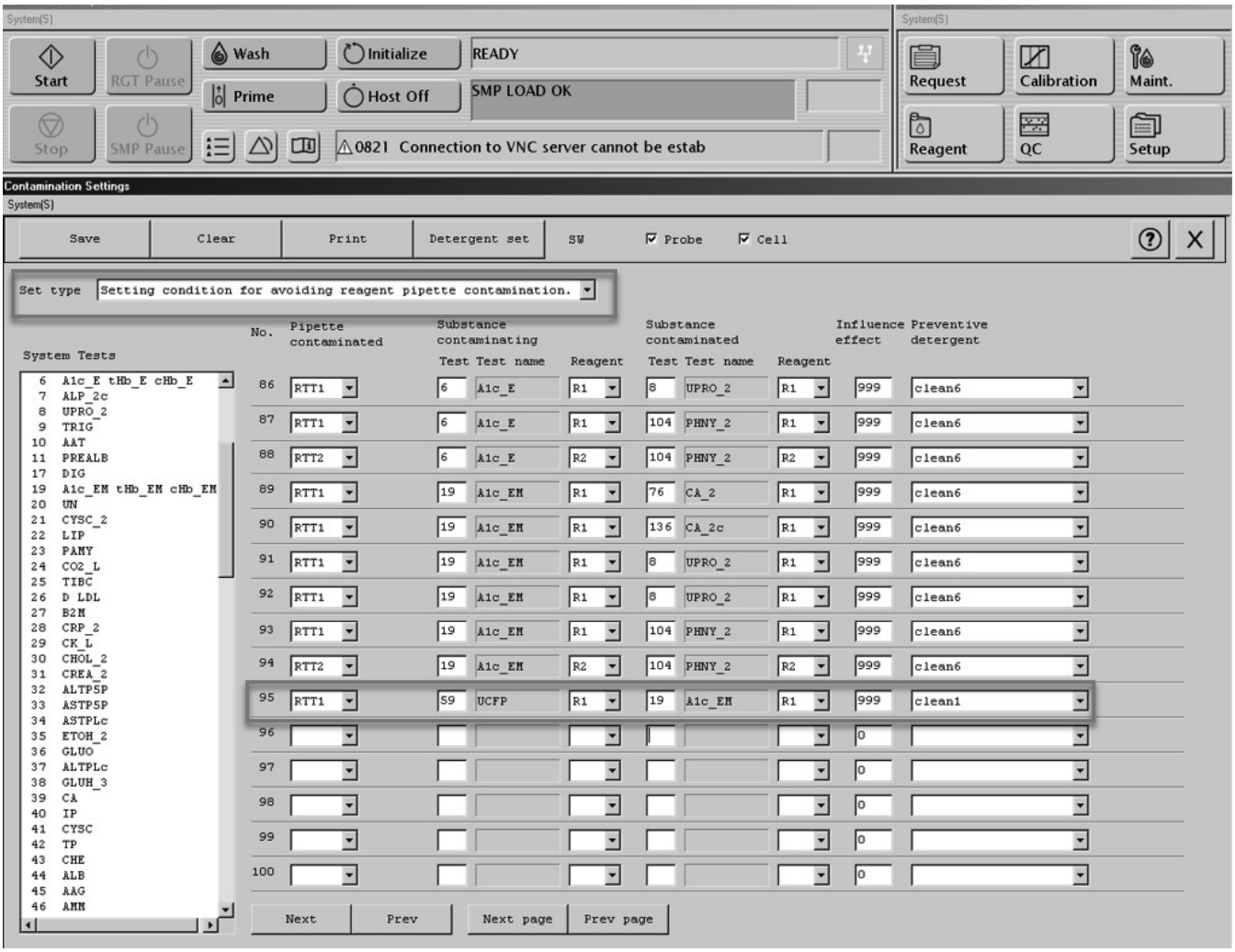
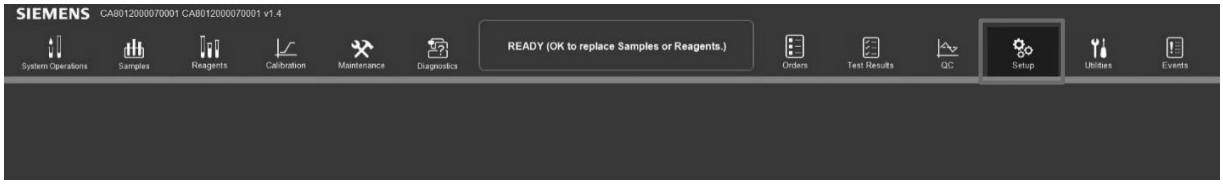


7. Select **Save** and **Yes** at the prompt.
8. Calibrate Hemoglobin A1c and verify performance by processing quality control.
9. Perform a system back up after the wash configuration is completed.

ADVIA Chemistry XPT System

1. Ensure system is in the Ready state.
2. Log in as LabManager.
3. Select **Setup** on the Menu Panel.



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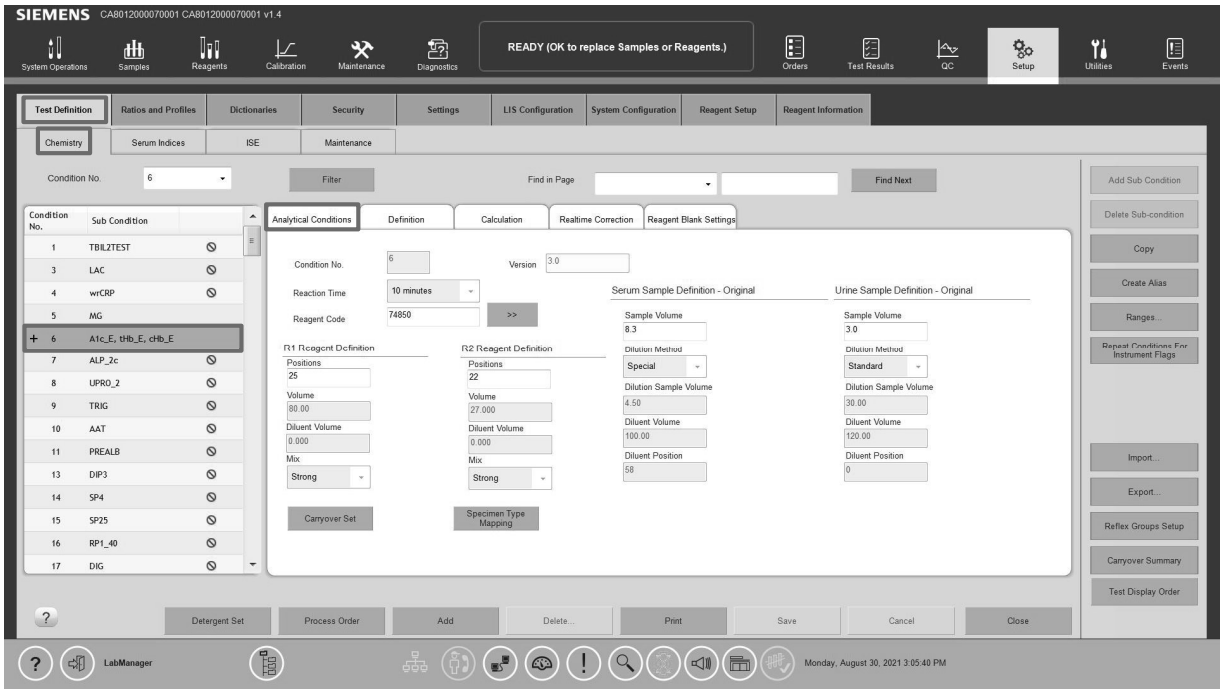
4. Select **Test Definition**
    a) Select **Chemistry** Tab
    b) Select the assay being contaminated from the Sub Condition window **(A1c_E, Condition No. 6 or A1c_EM, Condition No. 19).**
    c) Select the **Analytical Conditions** tab for the required assay.



5. **Add the Contamination Avoidance Settings**:

a) Select **Carryover Set** at the bottom of the Analytical Conditions Screen.

NOTE: DO NOT alter any existing contamination avoidance settings already configured.

b) Under Reagent Probe Contamination Select **Add**.
c) Use the drop down and select **RTT1** under the Contaminated Probe column.
d) Use the drop down and enter the contaminating assay **UCFP (Condition No. 59)** in the contaminating assay area.
e) Enter **999** for the Influence Effect.
f) Use the drop down and select **Clean1** as the preventative detergent.
Note: Probe Wash 1 is the same as Clean1.
g) Select **Continue.**
h) Once Continue is selected, a prompt will be received to Calibrate the updated assay. Select **Ok.**
i) Select **Save.**

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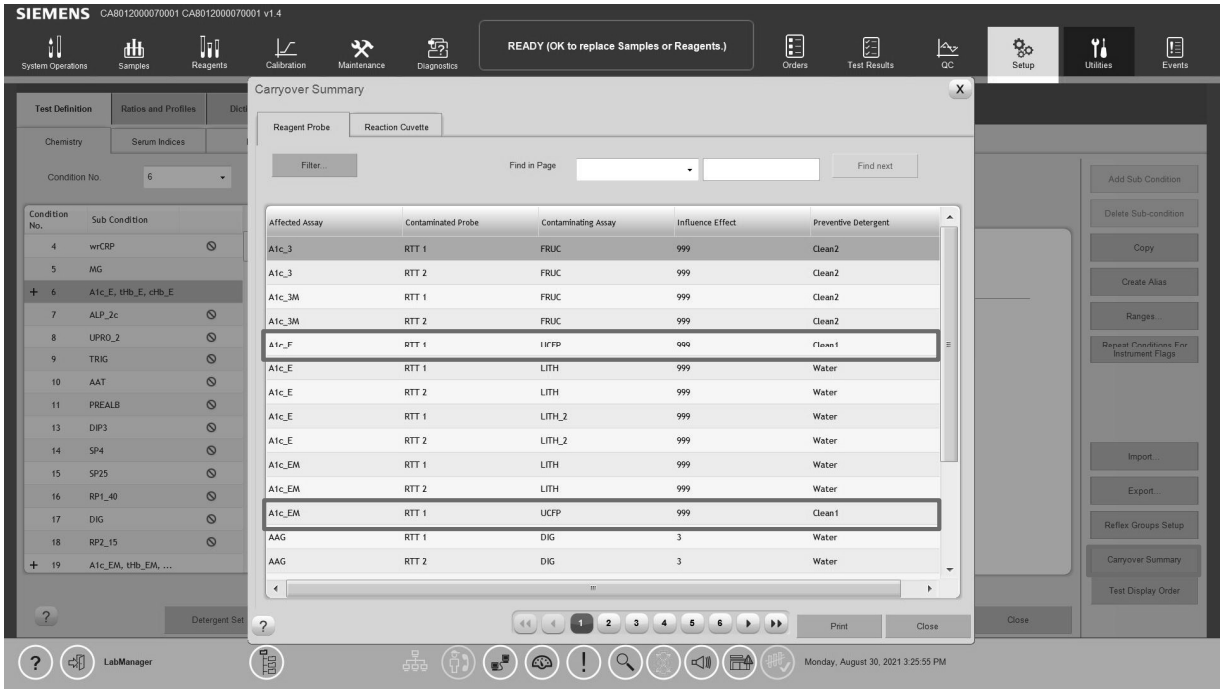
j) Verify the settings by selecting **Carryover Summary** on the right hand of the screen. Carryover Summary is a complete listing of all the Reagent Probe and Reaction Cuvette Carryover Mitigations for impacted assays.



6. Calibrate Hemoglobin A1c and verify performance by processing quality control.
7. Perform a system back up after the wash configuration is completed.

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FIELD CORRECTION EFFECTIVENESS CHECK

Falsely Depressed Enzymatic Hemoglobin A1c (A1c_E and A1c_EM) Results due to Reagent Carryover from the Urinary/Cerebrospinal Fluid Protein (UCFP) Assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, ACHC21-14.A.OUS.CHC dated September 2021 regarding Falsely Depressed Enzymatic Hemoglobin A1c (A1c_E and A1c_EM) Results due to Reagent Carryover from the Urinary/Cerebrospinal Fluid Protein (UCFP) Assay. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter.	Yes ☐	No ☐
2. Is your laboratory currently running UCFP on the ADVIA Chemistry System(s)?	Yes ☐	No ☐
3. Is your laboratory currently running A1c_E/A1c_EM on the same ADVIA Chemistry System(s)?	Yes ☐	No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

If you have any questions, contact your local Siemens Healthineers technical support representative.

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