

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



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 10 working 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.

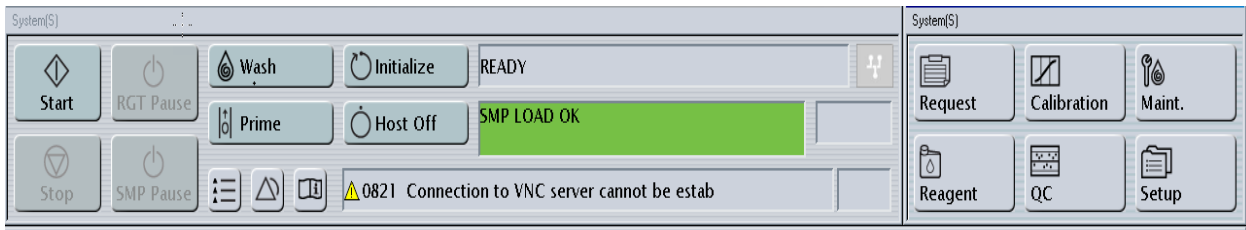
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative at 1800-888-872.

Additional Information

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

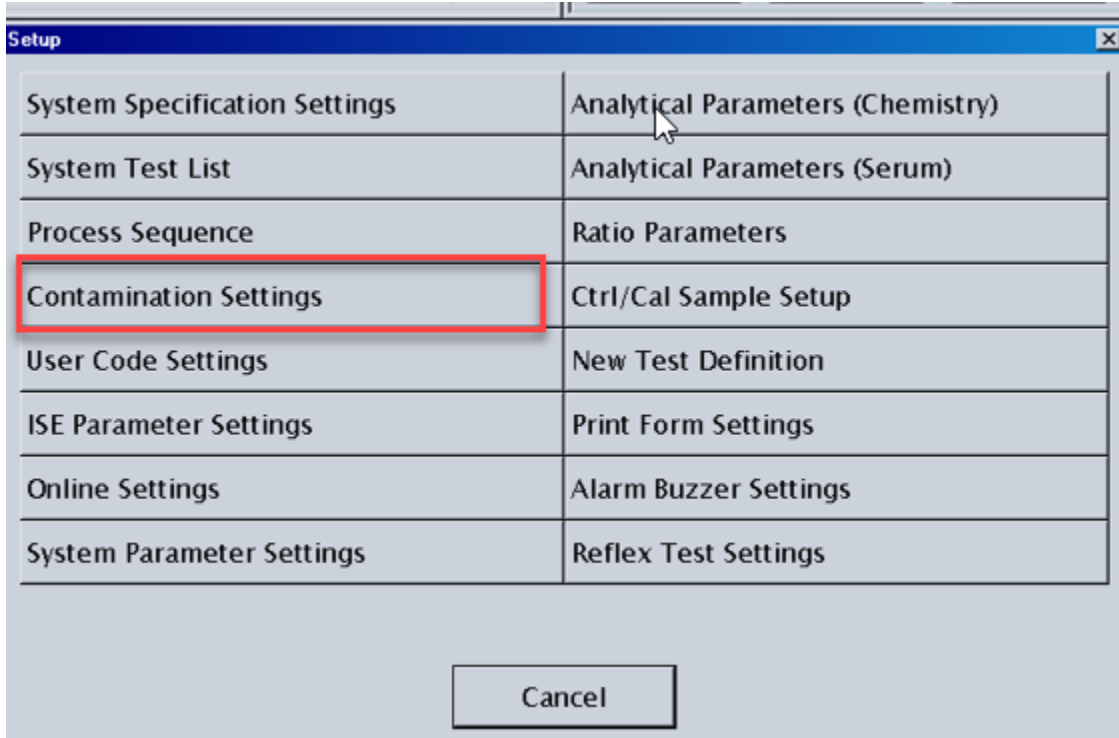
ADVIA 1800/2400 Chemistry System

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



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

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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System(S) READY SMP LOAD OK

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Request Calibration Maint. Reagent QC Setup

Contamination Settings

System(S) Save Clear Print Detergent set SW Probe Cell

Set type: Setting condition for avoiding reagent pipette contamination.

System Tests	No.	Pipette contaminated	Substance contaminating			Substance contaminated			Influence preventive effect	Preventive detergent
			Test	Test name	Reagent	Test	Test name	Reagent		
6 A1c_E tHb_E cHb_E	86	RTT1	6	A1c_E	R1	8	UPRO_2	R1	999	clean6
7 ALP_2c	87	RTT1	6	A1c_E	R1	104	PHNY_2	R1	999	clean6
8 UPRO_2	88	RTT2	6	A1c_E	R2	104	PHNY_2	R2	999	clean6
9 TRIG	89	RTT1	19	A1c_EM	R1	76	CA_2	R1	999	clean6
10 AAT	90	RTT1	19	A1c_EM	R1	136	CA_2c	R1	999	clean6
11 PREALB	91	RTT1	19	A1c_EM	R1	8	UPRO_2	R1	999	clean6
17 DIG	92	RTT1	19	A1c_EM	R1	8	UPRO_2	R1	999	clean6
19 A1c_EM tHb_EM cHb_EM	93	RTT1	19	A1c_EM	R1	104	PHNY_2	R1	999	clean6
20 UN	94	RTT2	19	A1c_EM	R2	104	PHNY_2	R2	999	clean6
21 CYSC_2	95	RTT1	59	UCFP	R1	6	A1c_E	R1	999	clean1
22 LIP	96								0	
23 PAMY	97								0	
24 CO2_L	98								0	
25 TIBC	99								0	
26 D LDL	100								0	
27 B2M									0	
28 CRP_2									0	
29 CK_L									0	
30 CHOL_2									0	
31 CREA_2									0	
32 ALTPSP									0	
33 ASTPSP									0	
34 ASTPLc									0	
35 ETOH_2									0	
36 GLUC									0	
37 ALTPLc									0	
38 GLUH_3									0	
39 CA									0	
40 IP									0	
41 CYSC									0	
42 TP									0	
43 CHE									0	
44 ALB									0	
45 AAG									0	
46 AMM									0	

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System(S) READY SMP LOAD OK

0821 Connection to VNC server cannot be estab

Request Calibration Maint. Reagent QC Setup

Contamination Settings

System(S)

Save Clear Print Detergent set SW Probe Cell

Set type: Setting condition for avoiding reagent pipette contamination.

System Tests	No.	Pipette contaminated	Substance contaminating			Substance contaminated			Influence preventive effect	Preventive detergent
			Test	Test name	Reagent	Test	Test name	Reagent		
6 A1c_E tHb_E cHb_E	86	RTT1	6	A1c_E	R1	8	UPRO_2	R1	999	clean6
7 ALP_2c	87	RTT1	6	A1c_E	R1	104	PHNY_2	R1	999	clean6
8 UPRO_2	88	RTT2	6	A1c_E	R2	104	PHNY_2	R2	999	clean6
9 TRIG	89	RTT1	19	A1c_EM	R1	76	CA_2	R1	999	clean6
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19 A1c_EM tHb_EM cHb_EM	93	RTT1	19	A1c_EM	R1	104	PHNY_2	R1	999	clean6
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21 CYSC_2	95	RTT1	59	UCFP	R1	19	A1c_EM	R1	999	clean1
22 LIP	96								0	
23 PAMY	97								0	
24 CO2_L	98								0	
25 TIBC	99								0	
26 D LDL	100								0	
27 B2M									0	
28 CRP_2									0	
29 CK_L									0	
30 CHOL_2									0	
31 CREA_2									0	
32 ALTPSP									0	
33 ASTPSP									0	
34 ASTPLc									0	
35 ETOH_2									0	
36 GLUO									0	
37 ALTPLc									0	
38 GLUH_3									0	
39 CA									0	
40 IP									0	
41 CYSC									0	
42 TP									0	
43 CHE									0	
44 ALB									0	
45 AAG									0	
46 AMM									0	

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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.

SIEMENS CAB012000070001 CAB012000070001 v1.4

System Operations Samples Reagents Calibration Maintenance Diagnostics

READY (OK to replace Samples or Reagents.)

Orders Test Results QC **Setup** Utilities Events

Siemens Healthcare Sdn Bhd [201501001338 (1126670-U)]
 Level 16 - Wing1 & 2, CP Tower,
 No 11, Jalan 16/11,
 Pusat Dagang Seksyen 16,
 46350 Petaling Jaya,
 Selangor Darul Ehsan, Malaysia

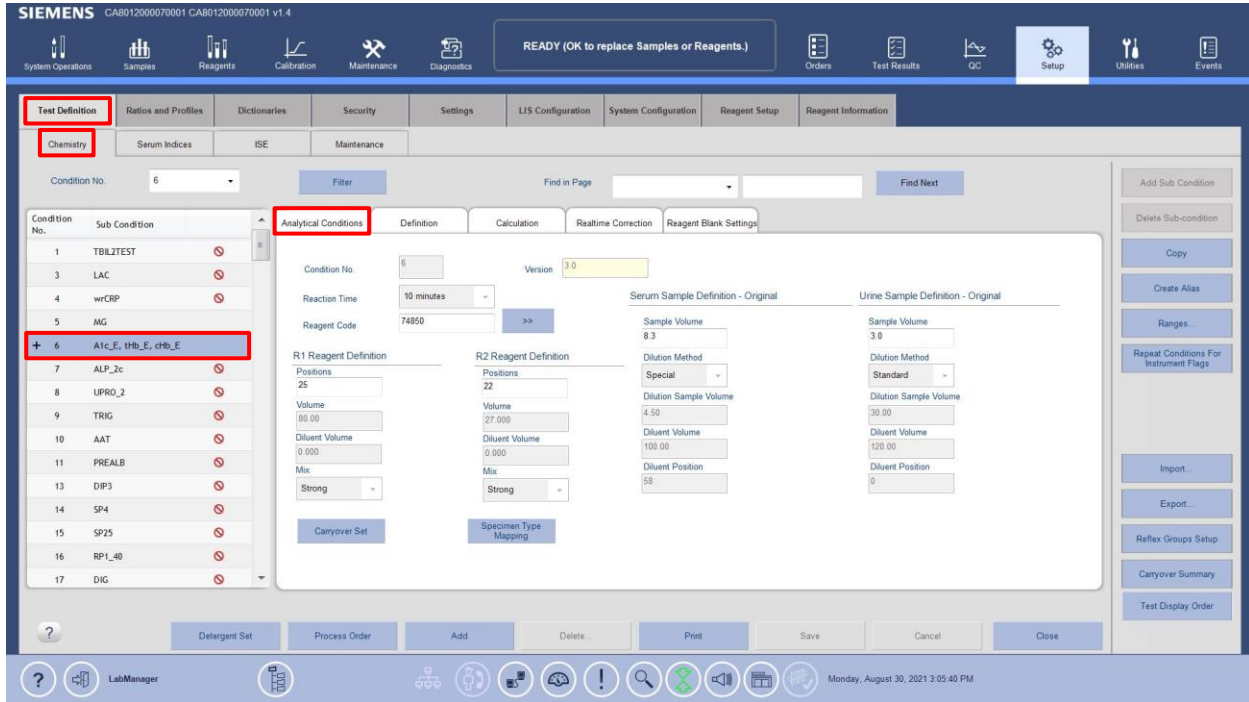
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www.siemens-healthineers.com/en-my

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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.



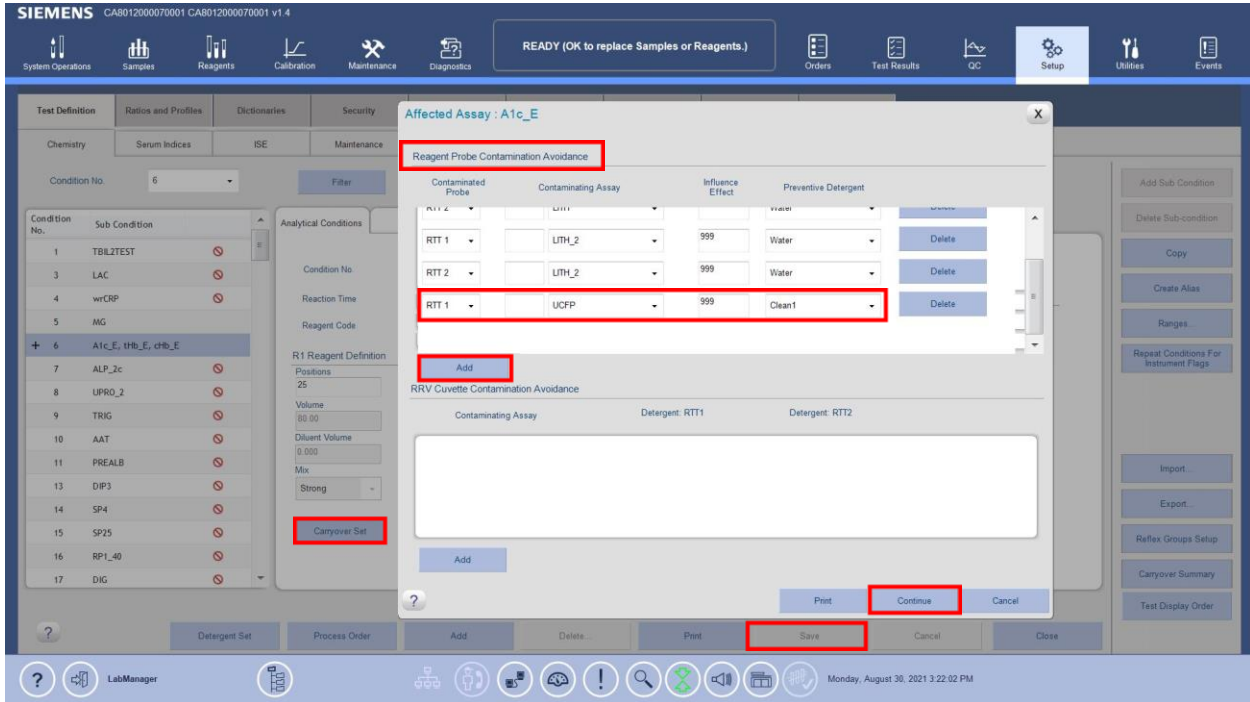
5. **Add the Contamination Avoidance Settings:**

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

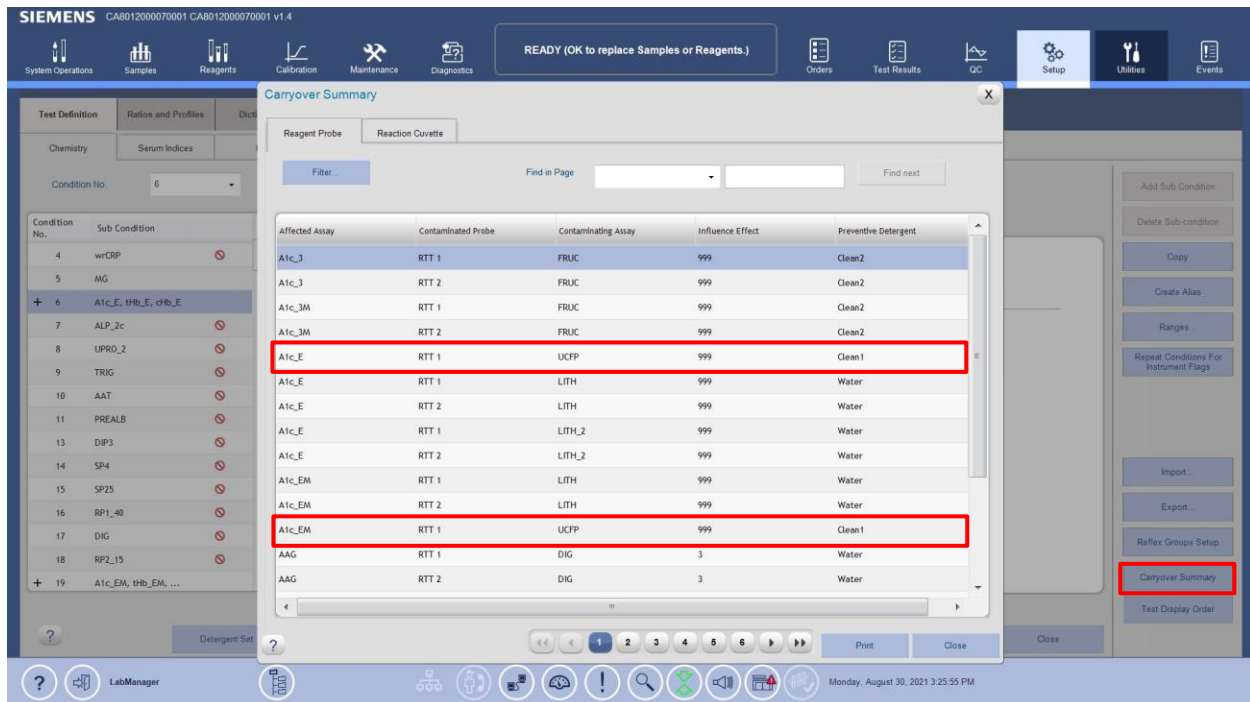
NOTE: DO NOT alter any existing contamination avoidance settings already configured.

- 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.

ADVIA is a trademark of Siemens Healthcare Diagnostics Inc.

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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 Sdn Bhd 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 fscareportingunit.my@siemens-healthineers.com

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