

September 2021

## ADVIA<sup>®</sup> 1800 Chemistry System ADVIA<sup>®</sup> 2400 Chemistry System ADVIA<sup>®</sup> 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.

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

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

System(S)					System(S)	
$\Diamond$	U U	& Wash	) 🕐 Initialize	READY 4	Đ	16
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Stop	SMP Pause		0821 Connec	tion to VNC server cannot be estab	Reagent	Setup

## 4. Select Contamination Settings

etup	
System Specification Settings	Analytical Parameters (Chemistry)
System Test List	Analytical Parameters (Serum)
Process Sequence	Ratio Parameters
Contamination Settings	Ctrl/Cal Sample Setup
User Code Settings	New Test Definition
ISE Parameter Settings	Print Form Settings
Online Settings	Alarm Buzzer Settings
System Parameter Settings	Reflex Test 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**

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

System(5)								System(5)		
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System Tests	No.	Pipette contaminated	Substance contaminating Test Test name	Reagent	Substance contaminated Test Test name	Inf eff Reagent	fluence fect	e Preventive detergent		
6 A1c_E tHb_E cHb_E	86	RTT1 ·	6 Alc_E	R1 •	8 UPRO_2	R1 💌	999	clean6	•	
8 UPRO_2 9 TRIG	87	RTT1 ·	6 Alc_E	R1 •	104 PHNY_2	R1 💌	999	clean6	*	
10 AAT 11 PREALB	88	RTT2 ·	6 Alc_E	R2 -	104 PHNY_2	R2 🔻	999	clean6	*	
17 DIG 19 Alc_EN tHb_EN cHb_EN 20 UN	89	RTT1 -	19 Alc_EM	R1 -	76 CA_2	R1 -	999	clean6	•	
21 CYSC_2 22 LIP	90	RTT1 ·	19 Alc_EM	R1 •	136 CA_2c	R1 •	999	clean6	•	
23 PANY 24 CO2 L	91	RTT1 ·	19 AIC_ER	R1 •	8 UPRO_2	R1 •	999	clean6	•	
25 TIBC 26 D LDL	92	RTT1 -	19 Alc_EN	R1 •	8 UPRO_2	R1 💌	999	clean6	•	
27 B2M 28 CRP_2	93	RTT1 -	19 Alc_EM	R1 -	104 PHNY_2	R1 -	999	clean6	•	
29 CK_L 30 CHOL_2	94	RTT2 -	19 Alc EN	R2 •	104 PHNY 2	R2 -	999	clean6	-	
31 CREA_2 32 ALTP5P 33 ASTP5P	95	RTT1 +	59 UCFP	R1 •	6 Alc E	R1 -	999	clean1	•	
34 ASTPLC 35 ETOH 2	98						0	-	-	
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40 IP 41 CYSC	99									
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Falsely Depressed Enzymatic Hemoglobin A1c (A1c\_E and A1c\_EM) Results due to Reagent Carryover from the Urinary/Cerebrospinal Fluid Protein (UCFP) Assay

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8 UPRO_2 9 TRIG	87	RTT1 -	6	A1c_E	R1	•	104	PHNY_2	R1	Ŧ	999	clean6	•	
10 AAT 11 PREALB	88	RTT2 •	6	A1c_E	R2	•	104	PHNY_2	R2	¥	999	clean6		
17 DIG 19 Alc_EM tHb_EN cHb_EN	89	RTT1 ·	19	A1c_EN	R1	•	76	CA_2	R1	•	999	clean6	•	
20 UN 21 CYSC_2 22 LTP	90	RTT1 ·	19	A1c_EH	R1	•	136	CA_2c	R1	•	999	clean6	-	
23 PANY 24 CO2 L	91	RTT1 ·	19	A1C_EH	R1	•	8	UPRO_2	R1	•	999	clean6		
25 TIBC 26 D LDL	92	RTT1 -	19	A1C_EH	R1	•	8	UPRO_2	R1	-	999	clean6	•	
27 B2M 28 CRP_2	93	RTT1 +	19	A1C_EN	R1	•	104	PHNY_2	R1	-	999	clean6		
29 CK_L 30 CHOL_2	94	RTT2 ·	19	Alc EH	R2	-	104	PHNY 2	R2	-	999	clean6	-	
32 ALTP5P 33 ASTP5P	95	RTT1 -	59	UCFP	R1	-	19	A1c EN	R1	-	999	clean1		
34 ASTPLC 35 ETOH 2	96				í-	-	F	-	-	-	0	1		
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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	CA801200007000 Samples	Reagents	Calibration	Maintenance	Diagnostics	READY (OK to replace Samples or Reagents.)	Orders	Test Results	< <u>₹</u> qc	Setup	<b>Ti</b> Utilities	Events

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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.

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Chemistry	Serum Indices	ISE	Maintenance									
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				~	Y	~	-					
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3 LAC	0	_	Condition No.		Version 3.0						Crea	e Alias
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5 MG		- 1	Reagent Code	74850	>>	Sample Volume 8.3		Sample Volume 3.0			Rar	gea
+ 6 A1c_E	, tHb_E, cHb_E		R1 Reagent Definition	R2 F	Reagent Definition	Dilution Method		Dilution Method			Repeat Co	inditions For ent Flags
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16 RP1_4	0 0										Con	r Summanı
17 DIG	0	-									Canyove	Gummary
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?	bManager	UTT		÷.				day, August 30, 2021 3:05	40 PM			

- 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.

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

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7	ALP_2c	0	Positions	Add						Instrument Flags
8	UPR0_2	0	25	RRV Cuvette Cor	tamination Avoidance					
9	TRIG	0	80.00	Contam	inating Assay	Detergent: RTT1	Detergent: RTT2			
10 .	AAT	0	Diluent Volume							
11 1	PREALB	0	Mix							Import
13	DIP3	0	Strong -	1						
14 :	SP4	0		-						Export
15	SP25	0	Carryover Set							Reflex Groups Setup
16	RP1_40	0		Add						
17	DIG	0 •					_	_		Carryover Summary
				2			Print	Continue	Cancel	Test Display Order
?		Detergent Set	Process Order	Add	Delete	Print	Save	Cancel	Close	
?	LabManager	(					Monday	, August 30, 2021 3:22:02	PM	

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.

SIEMEN	S CA8012000070001	CA80120000700	001 v1.4	C							-
System Operation	ons Samples	Reagents	Calibration M	aintenance Diagnostics	READY (OK to replace Sam	ples or Reagents.)	Orders Test Results	ac ac	<b>Ö</b> o Setup	Utilities	[] Events
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Conditio	on No. 6	•	Filter		Find in Page	•	Find next			Add S	lub Condition
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4	wrCRP	0	A1c_3	RTT 1	FRUC	999	Clean2				Сору
5	MG		A1c_3	RTT 2	FRUC	999	Clean2				eate Alias
+ 6	A1c_E, tHb_E, cHb_E		A1c_3M	RTT 1	FRUC	999	Clean2				
7	ALP_2c	0	A1c_3M	RTT 2	FRUC	999	Clean2			F	anges
8	UPRO_2	0	A1c_E	RTT 1	UCFP	999	Clean1	Ē		Repeat	Conditions For
9	TRIG	0	A1c_E	RTT 1	LITH	999	Water				anten ranga
10	AAT	0	A1c_E	RTT 2	LITH	999	Water				
11	PREALB	0	A1c_E	RTT 1	LITH_2	999	Water				
13	SB4	0	A1c_E	RTT 2	LITH_2	999	Water				
15	SP25	0	A1c_EM	RTT 1	LITH	999	Water			i	mport
16	RP1 40	0	A1c_EM	RTT 2	LITH	999	Water			E	Export
17	DIG	0	A1c_EM	RTT 1	UCFP	999	Clean1				
18	RP2_15	0	AAG	RTT 1	DIG	3	Water	_		Kenex	Groups Setup
+ 19	A1c_EM, tHb_EM,		AAG	RTT 2	DIG	3	Water	-		Canyo	iver Summary
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- 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.