

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

Falsely Depressed Enzymatic Creatinine (ECRE_2) Results due to Reagent Carryover from the Urinary/Cerebrospinal Fluid Protein (UCFP) Assay

Our records indicate that your facility has received the following product:

Table 1. ADVIA Chemistry Product

Assay	Test	Siemens Material	Unique Device Identification	Lot
	Code	Number (SMN)	(UDI)	Number
Urinary/Cerebrospinal Fluid Protein	UCFP	11319151	00630414279176	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 Creatinine_2 (ECRE_2). Falsely depressed ECRE_2 results may be observed when the assay is processed after the UCFP test on ADVIA Chemistry systems. Though testing was performed using Quality Control (QC) samples, a similar bias can be expected with patient samples and calibrators across the entire analytical measuring range. See Table 2 in "Additional Information" section for the worst-case and range of biases observed with QC samples.

Investigation of the issue indicates that the addition of a Clean 1 wash using Probe Wash 1 is an effective mitigation in preventing UCFP reagent carryover. Please follow the instructions in the "Actions to be Taken by the Customer" section below.

Risk to Health

This issue may lead to erroneously depressed creatinine patient results that is not expected to provide a clinically significant impact on patient management with negligible potential for injury. Sporadic QC or calibration failures, if any, are mitigated by standard laboratory procedures to enable uninterrupted generation of results to help guide patient care, as required by the clinical setting. Creatinine results would be correlated with the patient's clinical history, signs and symptoms, as well as other laboratory results.

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Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Perform the instructions provided in Additional Information.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- 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

Donor	Victim	Control mg/dL (µmol/L)	Control after donor mg/dL (μmol/L)	Absolute Bias mg/dL (µmol/L)
UCFP	ECRE_2	1.29 (114)	1.21 (107)	-0.08 (7)
UCFP	ECRE_2	1.35 (119)	1.14 (101)	-0.21 (18)
UCFP	ECRE_2	1.76 (156)	1.66 (147)	-0.10 (9)
UCFP	ECRE_2	1.84 (163)	1.58 (140)	-0.26 (23)
UCFP	ECRE_2	4.28 (378)	4.10 (362)	-0.18 (16)
UCFP	ECRE_2	4.39 (388)	4.02 (355)	-0.37 (33)
UCFP	ECRE_2	6.58 (582)	6.54 (578)	-0.04 (4)
UCFP	ECRE_2	6.83 (604)	6.62 (585)	-0.21 (19)
UCFP	ECRE_2	7.79 (689)	7.59 (671)	-0.20 (18)
UCFP	ECRE_2	8.09 (715)	7.55 (667)	-0.54 (48)

Table 2. Impact of UCFP carryover on ECRE_2 Results

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

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System(S)		System(S)	
♦ Start	Image: Wash Image: Im	Request	Calibration
Stop	Image: Some pause Image: Some pause Image: Some pause Image: Some pause Image: Some pause Image: Some pause	Reagent	QC Setup

4. Select Contamination Settings

Setup	×
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
	Cancel
	Curren

- 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 **ECRE_2 (48)** in the Substance contaminated area.
 - f) Use the drop down and select **R1** for the Reagent Probe.
 - g) Enter **999** for the Influence effect.

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h) Use the drop down and select **clean1** as the preventative detergent **Note: Probe Wash 1 is the same as clean1**

Stop SMP Pause	rime	Host C		R2(9) Cal Int		has	expire	2				lo Reagent		Setup
Contamination Settings														
Save Clear		Print	Deterger	nt set :	sw		🔽 Pr	obe 🗖 Ce	≥11					? X
Set type Setting condition :	for a	voiding reagent p	ipette con	tamination.	•									
System Tests	No.	Pipette contaminated		inating	Reag	ant		ance aminated Test name	Reag	et	fluenc) fect	e Preventive detergent		
900 All test 901 clean1(RTT1-53)	86	RTT1 -				.	8	UPRO_2	R1	-	999	clean6	•	
902 clean2(RTT1-54) 903 water (RTT1-56)	87	RTT1 -	6 A:	1c_E	R1	•	104	PHNY_2	R1	•	999	clean6	•	
904 clean5(RTT1-54) 905 clean6(RTT1-54) 906 clean1(RTT2-53)	88	RTT2 -	6 A:	1c_E	R2	•	104	PHNY_2	R2	•	999	clean6	•	
907 clean2(RTT2-54) 908 water (RTT2-56)	89	RTT1 💌	59 U	CFP	R1	•	48	ECRE_2	R1	•	999	clean1	•	
909 clean5(RTT2-54) 910 clean6(RTT2-54)	90	RTT1 -			R1	•			R1	•	999	vater	•	
3 LAC 4 wrCRP	91	RTT2 V		J	R2	•			R2	•	999	vater	•	
5 MG 6 Alc_E tHb_E cHb_E	92	RTT1 -			R1	-			R1	•	999	clean1	•	
7 ALP_2c 8 UPRO_2 10 AAT	93	RTT2 -			R2	•			R2	•	999	water	•	
11 PREALB 17 DIG	94	RTT1 -			R1	-			R1	•	999	water	•	
19 A1c_EM tHb_EM cHb_EM 20 UN	95	RTT1 -			R1	•			R1	•	999	clean6	•	
21 CYSC_2 22 LIP 23 PAMY	96	RTT2 -]	R2	-			R2	-	999	clean6	•	
25 FANT 25 TIBC 26 D LDL	97	RTT2 -			R2	•			R2	•	999	water	•	
27 B2M 28 CRP_2	98	RTT1 -			R1	-			R1	-	999	clean1	•	
29 CK_L 30 CHOL_2	99	RTT1 -			R1	•			R1	•	999	water	•	
31 CREA_2 32 ALTP5P 33 ASTP5P	100	RTT2 -		ļ	R2	•			R2	•	999	water	•	
34 ASTPLC		Next Pre	/	Next page	Pre	ev pa	ige							

- 7. Select **Save** and **Yes** at the prompt.
- 8. Calibrate ECRE_2 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.



- 4. Select Test Definition
 - a) Select Chemistry Tab

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- b) Select the assay being contaminated from the Sub Condition window (ECRE_2, Condition No. 48)
- c) Select the Analytical Conditions tab for the required assay.

SIEMEN	S CA8012000020001 C	A801200002000	1 v1.6								
System Operatio	ns Samples	Reagents	Calibration Maintenar		READY (OK to re	place Samples or Reagents.)	Orders Test Result		Setup	ti Utilities	Events
Test Definit		-	,	Settings	LIS Configuration	System Configuration Reagent Setup	Reagent Information				
Chemistry	y Serum Indices	ISE	E Maintenance								
Conditio	48 48	~	Filter		Find in Page	~	Find	Next		Add Sub	b Condition
Condition No.	Sub Condition 🔺	^	Analytical Conditions	Definition	Calculation Realtime	Correction Reagent Blank Settings				Delete Su	ub-condition
17	DIG	0		10						C	юру
13	DIP3	0	Condition No.	48	Version 1.0						
26	DLDL	0	Reaction Time	10 minutes		Serum Sample Definition - Original	Urine Sample	Definition - Original		Creat	te Alias
171	EcrDM	_	Reagent Code	74330	>>	Sample Volume	Sample Volu	ne		Ran	iges
48	ECRE_2					13.0	13.0			Repeat Co	anditions For
85	ECre3		R1 Reagent Definition Positions		2 Reagent Definition Positions	Dilution Method Standard	Dilution Meth Special	lod			ent Flags
188	ECre3_1					Dilution Sample Volume	Dilution Sam	ple Volume			
189	ECre3_2		Volume 80.00		Volume 27.000	30.00	3.00				
190	ECre3_3		Diluent Volume		Diluent Volume	Diluent Volume 120.00	Diluent Volum 147.00	ne			
181	EcreC1_20X		0.000 Mix		0.000	Diluent Position	Diluent Posit	ion		Imp	port
174	EcrHC		Weak		Mix Weak ~	0	0				011
+ 173	EcrHN, EcrC1New									Exp	port
35	ETOH_2	0	Carryover Set		Specimen Type Mapping					Define Co	roups Setup
101	FRT	0								Reflex Gr	notes Setup
115	FRUC	~								Carryove	er Summary
			-								

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.

agent Probe Contan	nination Avoidance		A				
Contaminated Probe	Contaminating Ass	ay	Influence Effect	Preventive De	tergent		
RTT 1 ~	ACET	~	10	Clean2	~	Delete	
RTT 2 v	ACET	~	10	Clean2	~	Delete	
RTT 1 🗸	UCFP	~	999	Clean1	~	Delete	
Add v Cuvette Contarmir	nation Avoidance						
		Detergent	t: RTT1	Detergent: F	.TT2		
v Cuvette Contarnir		Detergent	t: RTT1	Detergent: F	TT2		
v Cuvette Contarnir		Detergent	:: RTT1	Detergent: F			
v Cuvette Contarnir		Detergent	: RTT1	Detergent: F	TT2		

 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

Reagent Probe	Reaction Cuvette			
Filter	1	Find in Page Contaminated Pr	obe v	Find next
Affected Assay	Contaminated Prob	e Contaminating Assay	Influence Effect	Preventive Detergent
ECRE_2	RTT 2	ACET	10	Clean 2
ECRE_2	RTT 1	UCFP	999	Clean 1
ECre3	RTT 1	GENT_2	999	Clean 1
ECre3	RTT 2	GENT_2	999	Clean 1
ECre3	RTT 1	XTC	999	Water
ECre3	RTT 2	XTC	999	Water
ECre3	RTT 1	TOB_2	999	Clean5
ECre3	RTT 1	TOB_2	999	Clean 1
ECre3	RTT 2	TOB_2	999	Clean5
ECre3	RTT 2	TOB 2	999	Clean 1

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- 6. Calibrate ECRE_2 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 Creatinine (ECRE_2) 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 (UFSN), CHC23-01.A.OUS dated July 2023, regarding Falsely Depressed Enzymatic Creatinine (ECRE_2) 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 ECRE_2 on the same ADVIA Chemistry System(s)?	Yes 🗆	No 🗆

Name of person completing questionnaire:

Title:	
Institution:	Instrument Serial Number:
Street:	
City:	State:
Phone:	Country:

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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