Urgent Field Safety Notice

CHC23-01.A.OUS

July 2023

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 Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot 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.

511 Benedict Avenue
Tarrytown, N.Y. 10591

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

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

Table 2. Impact of UCFP carryover on ECRE_2 Results

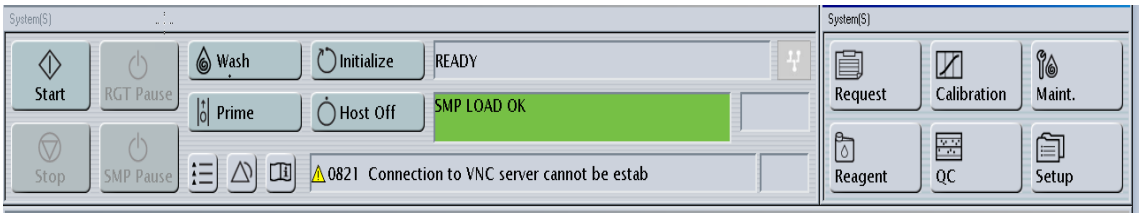
Donor	Victim	Control mg/dL (µmol/L)	Control after donor mg/dL (µmol/L)	Absolute Bias mg/dL (µmol/L)
UCFP	ECRE_2	1.29 (114)	1.21 (107)	-0.08 (7)
UCFP	ECRE_2	1.35 (119)	1.14 (101)	-0.21 (18)
UCFP	ECRE_2	1.76 (156)	1.66 (147)	-0.10 (9)
UCFP	ECRE_2	1.84 (163)	1.58 (140)	-0.26 (23)
UCFP	ECRE_2	4.28 (378)	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)

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

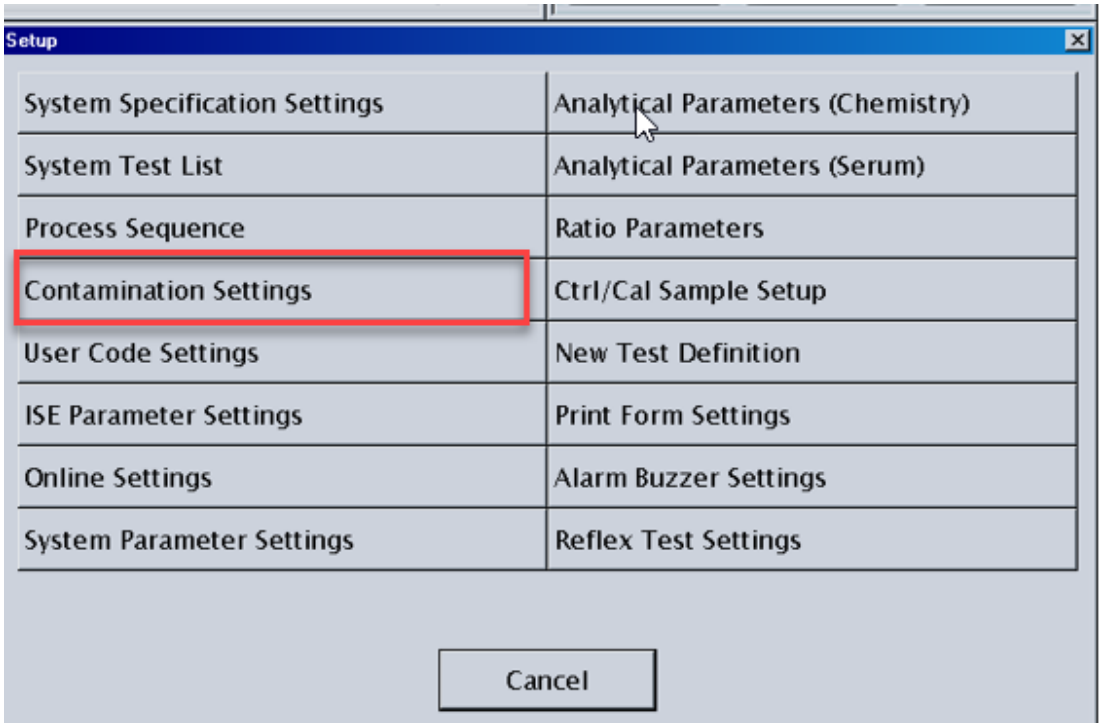
ADVIA 1800/2400 Chemistry System

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

511 Benedict Avenue
Tarrytown, N.Y. 10591



4. Select **Contamination Settings**



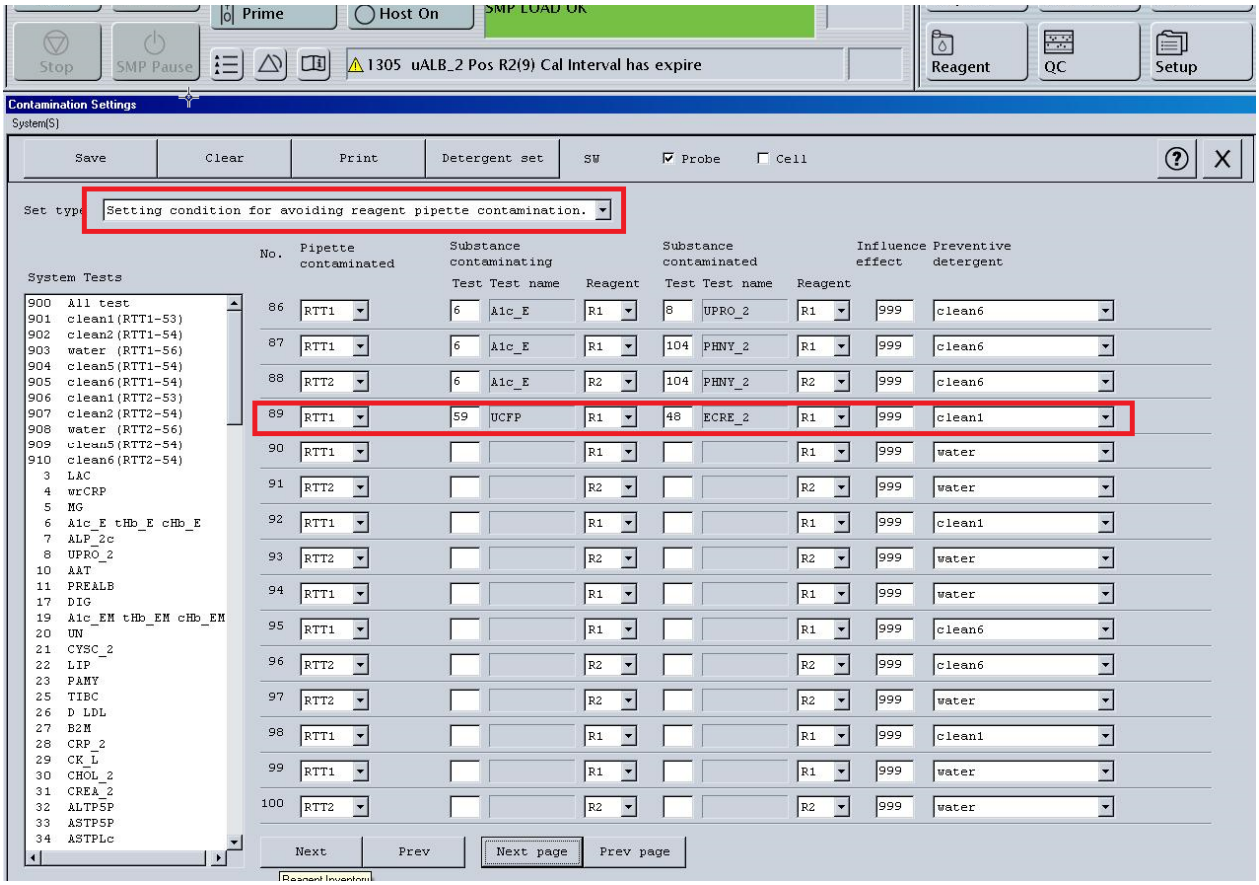
5. Select the **Next Page** button until you come to the next available usable area. NOTE: Do not leave spaces or type over existing listings.

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 **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.

511 Benedict Avenue
Tarrytown, N.Y. 10591

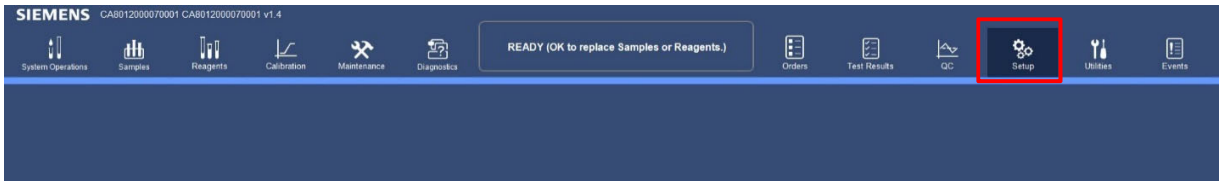
h) Use the drop down and select **clean1** as the preventative detergent
Note: Probe Wash 1 is the same as clean1



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

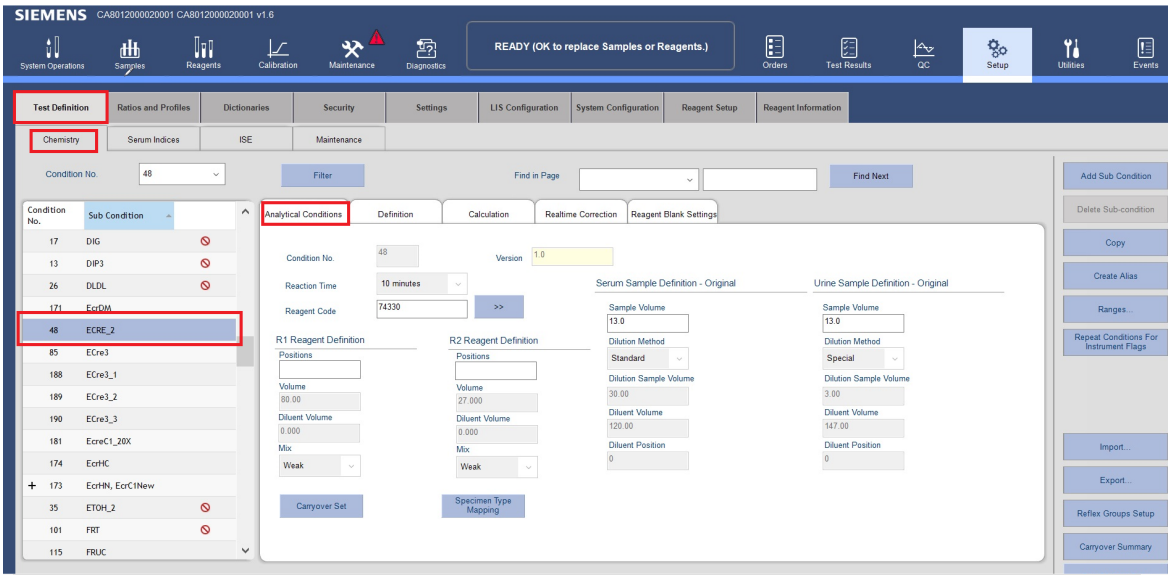
1. Ensure system is in the Ready state.
2. Log in as LabManager.
3. Select **Setup** on the Menu Panel.



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

511 Benedict Avenue
Tarrytown, N.Y. 10591

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.



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.

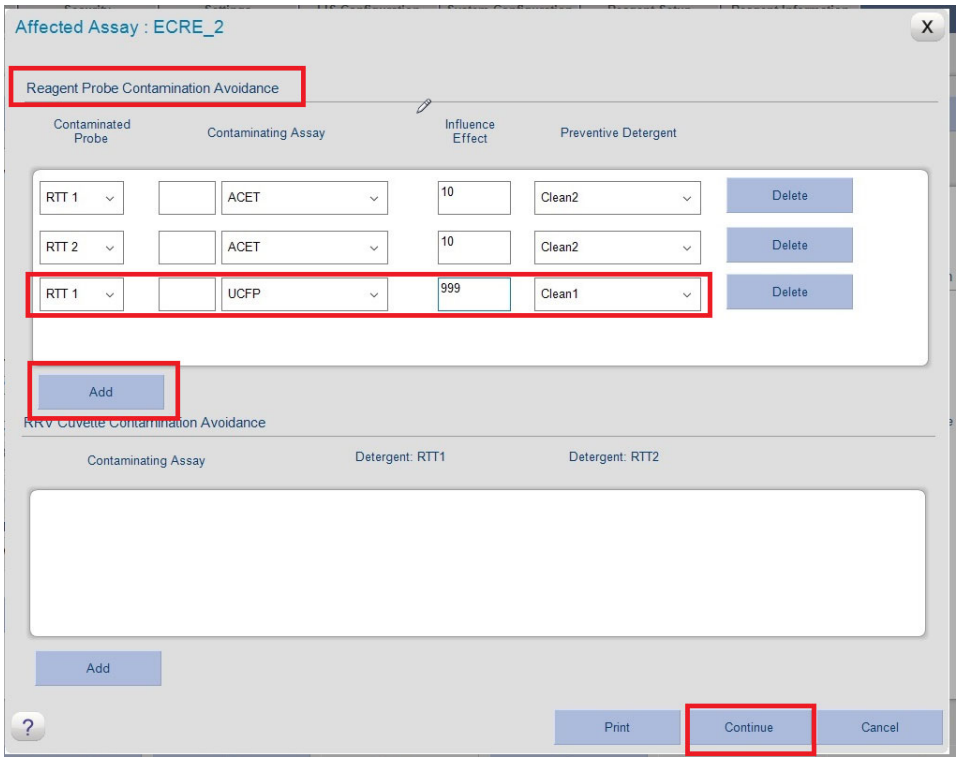
   b) Under Reagent Probe Contamination Select **Add**
   c) Use the drop down and select **RTT1** under the Contaminated Probe column.
   d) Use the drop down and enter the contaminating assay **UCFP (Condition No. 59)** in the contaminating assay area.
   e) Enter **999** for the Influence Effect.
   f) Use the drop down and select **Clean1** as the preventative detergent.

   Note: Probe Wash 1 is the same as Clean1.

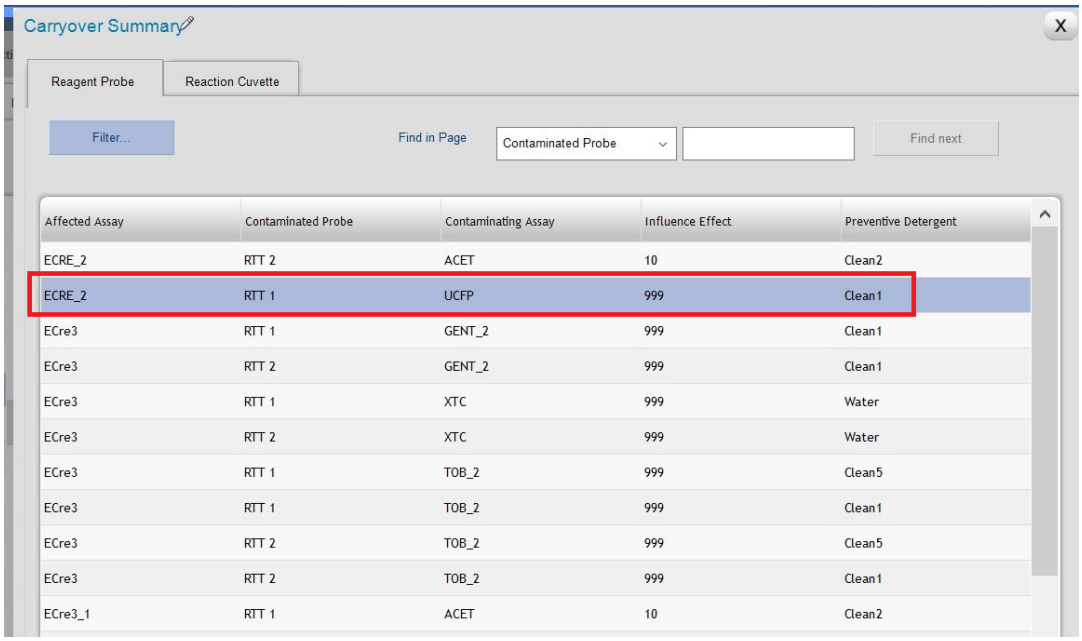
   g) Select **Continue.**
   h) Once Continue is selected, a prompt will be received to Calibrate the updated assay. Select **Ok.**
   i) Select **Save.**

511 Benedict Avenue
Tarrytown, N.Y. 10591

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



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



511 Benedict Avenue
Tarrytown, N.Y. 10591

6. Calibrate ECRE_2 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.

511 Benedict Avenue
Tarrytown, N.Y. 10591

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

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.

511 Benedict Avenue
Tarrytown, N.Y. 10591