

Urgent Field Safety Notice

094D0090-02

2008-06

ADVIA® 1200 Chemistry Systems

Correcting Reagent Onboard Stability and Calibration Interval Values for Certain Methods on ADVIA 1200 Systems Running System Software V. 2.00.10

Our records indicate your ADVIA® 1200 System was updated with System Software V. 2.00.10. Siemens Healthcare Diagnostics determined that this software version referenced default reagent onboard stability (OBS) and calibration frequency (Cal Interval) values for some methods that differ from the actual method claim as stated in the method Instructions for Use. The software uses these values to track OBS (Days Remaining) and Cal Interval in the Reagent Inventory window.

For laboratories that use the software default values to flag Days Remaining and the Cal Interval, the methods affected by incorrect default OBS and Cal Interval values are in one of two possible classifications:

- Methods with incorrect default OBS and/or Cal Interval values that are **greater than** the actual method claim

In this case, the Reagent Inventory window does not flag the reagent at the appropriate time (Days Remaining incorrect) or you would not receive an accurate warning for calibration (Cal Interval incorrect). It is most likely that laboratory QC results would detect an onboard stability or calibration frequency problem, provided that the laboratory routinely runs quality control samples.

If QC samples are not run on a regular basis, a look back is required for those samples that were possibly run with reagents or calibration frequency beyond Siemens stated claim. The incorrect, default OBS and/or Cal Interval values for these methods are highlighted in Table 1.

- Methods with default OBS and/or Cal Interval values that are **less than** the actual method claim

In this case, the Reagent Inventory window would flag onboard stability expiration (Days Remaining incorrect) or calibration warning (Cal Interval incorrect) prematurely.

There is no risk in running these methods, but you would be calibrating more frequently than necessary and/or removing reagent containers prematurely.

To avoid the potential for further problems, Siemens Healthcare Diagnostics is conducting a field correction for systems already updated with System Software V. 2.00.10. Perform the following procedure to manually update the OBS and Cal Interval default values, on the ADVIA 1200 workstation computer, for the methods listed in Table 1.

Siemens Healthcare Diagnostics Inc.

511Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

Page 1 of 5

Procedure

1. Log on the ADVIA 1200 system as **supervisor**.
2. Put the system in the **READY** mode.
3. At the Menu Panel, select **Reagent**.
4. Select **Reagent Information** to display the Reagent Information window.
5. Perform the following edits for each Method listed in Table 1 that is in use on the system:
NOTE: Only edit the Days Remaining and Cal Interval fields if a value exists in Table 1. No change is required for those fields left blank in Table 1.
 - a. Enter the value from the Correct OBS column in the **Days Remaining** field.
 - b. Enter the value from the Correct Cal Interval column in the **Cal Interval** field.
6. Select the **Save** button to save the changes.
7. Print the contents of the Reagent Information window as follows:
 - a. Press the **Alt + Print Screen** keys.
 - b. Scroll down to populate the window with the next methods.
 - c. Repeat steps 7a and 7b until all methods have been printed.
8. Verify that edits made during step 5 are correct by comparing the printouts (generated in step 7) to the data in Table 1.
9. Select the **Save** button to save any changes.
10. Close the Reagent Information window.
11. Scan the reagent barcodes:
 - a. At the Menu Panel, select **Reagent**.
 - b. Select **Reagent Inventory**.
 - c. Select **Barcode Scan**.
12. Close the Reagent Inventory window.
13. Perform your laboratory-specific QC protocol to verify proper system functionality.

Table 1. Correct OBS (Days Remaining) and Cal Interval Values (Methods with incorrect values GREATER THAN the method claim are highlighted.)

Method Name	Reagent Code	OBS Values		Cal Interval Values	
		Correct	Incorrect	Correct	Incorrect
ACET	74363	42 (60 with RCI)*	14	7	14
ALB	74011	60	28		

Correcting Reagent Onboard Stability and Calibration Frequency Values for Certain Methods on ADVIA 1200 Systems Running System Software V. 2.00.10

Method Name	Reagent Code	OBS Values		Cal Interval Values	
		Correct	Incorrect	Correct	Incorrect
ALP AMP	74040	7	10		
ALP DEA	74041	30	14		
AAT	74055			30	7
ALT	74046	60	14		
AMM	74047	30	13	30	1
AMYLAS	74042	30	21		
APO A1	74085	14	7	14	7
APO B	74086	30	5	30	5
AST	74045	60	10		
ASTP5P	74045	30	10		
C4	74070			7	14
CARB	74032	14	30	14	30
CHE	74026	12 (40 with RCI)*	7		
CHOL	74014	60	21		
CK NAC	74043	10	5		
CO2_L	74362			1	30
DBIL_2	74074	14	60	14	30
D-HDL	74073	60	30	60	30
DIG	74029	30	7		
ETOH	74365	60	30		
GGT	74044	30	14		
GLUO	74020	60	14		
HAPT	74071	30	7	30	14
HbA1c	74039	50	30		
LAC	74051	60	25	24	45
LIP	74050	12	10	12	10
LITH	74257	30 (45 with RCI)*	30		
MG	74064	4 (10 with RCI)*	4	4 (10 with RCI)*	21
PREALB	74053			4	7
RF	74088	60	14	60	3

Correcting Reagent Onboard Stability and Calibration Frequency Values for Certain Methods on ADVIA 1200 Systems Running System Software V. 2.00.10

Method Name	Reagent Code	OBS Values		Cal Interval Values	
		Correct	Incorrect	Correct	Incorrect
SAL	74364	45	60	45	60
THC	74104			14	7
TOB	74058	30	14		
TRIG	74023	60	21	60	45
UA	74021	60	21		
μALB	74090			15	20
wrCRP	74038	35	21		

* As described in the *Instructions for Use* for this method, use of reagent container inserts (RCI) improves the stabilities of these reagents and calibrations. Use the "with RCI" values if you use inserts for these methods on your instruments.

Please complete the attached Completion Notification Form and fax it to the appropriate number provided on the form.

If you have any questions or need additional information, please contact your local technical support provider or distributor.

We apologize for any inconvenience this may have caused.

Thank you for your continuing support of Siemens Healthcare Diagnostics products.

ATTACHMENT A

Completion Notification Form

Complete this form and fax it to the appropriate number provided below. Submitting this form indicates you have received this information and updated the Days Remaining and Cal Interval values for the methods specified in the attached notice.

General Information

Institution Name: _____
System Model: _____
Serial Number: _____
State/Country: _____

Fax Information

USA: 877-229-3799 _____
Outside USA: Please return this form to your local Siemens Healthcare
Diagnostics office or distributor. _____

I have received Urgent Field Safety Notice 094D0090-02, *Correcting Reagent Onboard Stability and Calibration Interval Values for Certain Methods on ADVIA 1200 Systems Running System Software V. 2.00.10*, and I have made the corrections as described.

Signature: _____ **Date:** _____

Printed Name & Title: _____