



# Urgent Field Safety Notice

<b>Notice Ref No:</b>	< reference number >
<b>Document Date:</b>	26 Nov 2007

<b>PRODUCT AFFECTED:</b>	LIPC Lipase colorimetric LDL_C LDL-Cholesterol
<b>SYSTEM AFFECTED:</b>	cobas c 111
<b>MATERIAL NUMBERS:</b>	LDL_C Cat. No. 04 657578 190 LIPC Cat. No. 04 995767 190
<b>LOT NO (IF APPLICABLE):</b>	All lots
<b>SUMMARY OF ISSUE:</b>	<b>Carry-over from LDL-Cholesterol assay to Lipase assay on cobas c 111</b>
<b>ACTION REQUIRED:</b>	<b>Implementation of an extra wash cycle</b>
<b>CONTACTS:</b>	Technical Services: Country:

## Reason for notice

### **Carry-over from LDL-Cholesterol to the assay Lipase colorimetric on cobas c 111**

Dear Customer

The R2 reagent of the LDL-Cholesterol (Cat. No. 04 657578 190) shows a carry-over effect on the Lipase assay (Cat. No. 04 995767 190). Serum samples are affected, with an up to 50 U/L increased Lipase recovery observed.

Root cause:

The high concentration of Cholesterol-esterase in the start reagent R2 of LDL-Cholesterol is not adequately washed from the reagent probe by the standard wash procedure.

The carry-over occurs when **R1** reagent of Lipase is pipetted after **R2** of LDL-Cholesterol on cobas c 111.

**Consequence:**

Roche advises you to perform an extra wash cycle whenever both assays (LDL-Cholesterol and Lipase) are used on cobas c 111 systems.

Extra wash cycles using the cleaner Cat. No. 04774248 190 are designed to improve the effectiveness of reagent probe cleaning. They are only required for specifically defined combinations. Wash cycles can be added by the customer as needed.

**Action required:**

The Extra Wash Cycle setting must be installed manually on the cobas c 111 as defined below. The instruction for use the LIPC assay will be updated in due time.

Utilities

**Rule**

Active	On
Action	After
Trigger-Bottle	Code 059
Pipetting Type	Start Reagent
Cleaner-Bottle	Code 947
Volume	100.0

We apologize for any inconvenience this problem may cause you.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

Kind regards,



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<b>PRODUCT AFFECTED:</b>	LIPC; Lipase colorimetric LDL_C; LDL-Cholesterol plus 2 <sup>nd</sup> generation
<b>SYSTEM AFFECTED:</b>	COBAS INTEGRA <sup>®</sup> 400 and 400 plus
<b>MATERIAL NUMBERS:</b>	LDL_C            Cat. No. 03038866 322 LIPC             Cat. No. 03029590 322
<b>LOT NO (IF APPLICABLE):</b>	All lots
<b>SUMMARY OF ISSUE:</b>	<b>Carry-over from LDL-Cholesterol assay to Lipase assay on COBAS INTEGRA<sup>®</sup> 400/400 plus</b>
<b>ACTION REQUIRED:</b>	<b>Implementation of an extra wash cycle</b>
<b>CONTACTS:</b>	Technical Services: Country:

## Reason for notice

### **Carry-over from LDL-Cholesterol plus 2<sup>nd</sup> generation to the assay Lipase colorimetric on COBAS INTEGRA<sup>®</sup> 400/400 plus**

Dear Customer

The R2 reagent of the LDL-Cholesterol 2<sup>nd</sup> gen assay (LDL\_C Cat. No. 03038866 322) shows a carry-over effect on the Lipase assay (LIPC Cat. No. 03029590 322). Serum samples are affected, with an up to 50 U/L increased Lipase recovery observed.

Root cause:

The high concentration of Cholesterol-esterase in the start reagent R2 of LDL-Cholesterol is not adequately washed from the reagent probe by the standard wash procedure.

The carry-over occurs when **R1** reagent of Lipase is pipetted after **R2** of LDL-Cholesterol on COBAS INTEGRA<sup>®</sup> 400/400plus, which pipettes both reagents using the same probe. COBAS INTEGRA<sup>®</sup> 700/800 is not affected. On the COBAS INTEGRA<sup>®</sup> 700/800 R2 of LDL-C and R1 of LIPC cannot be pipetted with the same reagent probe.

**Consequence:**

Roche advises you to perform an extra wash cycle whenever both cassettes (LDL\_C and LIPC) are used on COBAS INTEGRA® 400/400 plus systems.

Extra wash cycles using the cleaner cassette Cat. No. 20764337, System-ID 07 6433 7 are designed to improve the effectiveness of reagent probe cleaning. They are only required for specifically defined combinations. Wash cycles can be added by the customer as needed.

**Action required:**

The Extra Wash Cycle setting must be installed manually on the COBAS INTEGRA® 400/400 plus as described in the chart below and in the attachment. The Extra Wash Cycle List which is implemented in the COBAS INTEGRA® Method Manual in the chapter Introduction / Extra Wash Cycles will be updated in due time.

Test combination in use		Extra Wash Cycle Configuration				
		Type	Test	Component	With	Volume
LDL_C	LIPC	after	LDL_C	SR	CLEAN	150

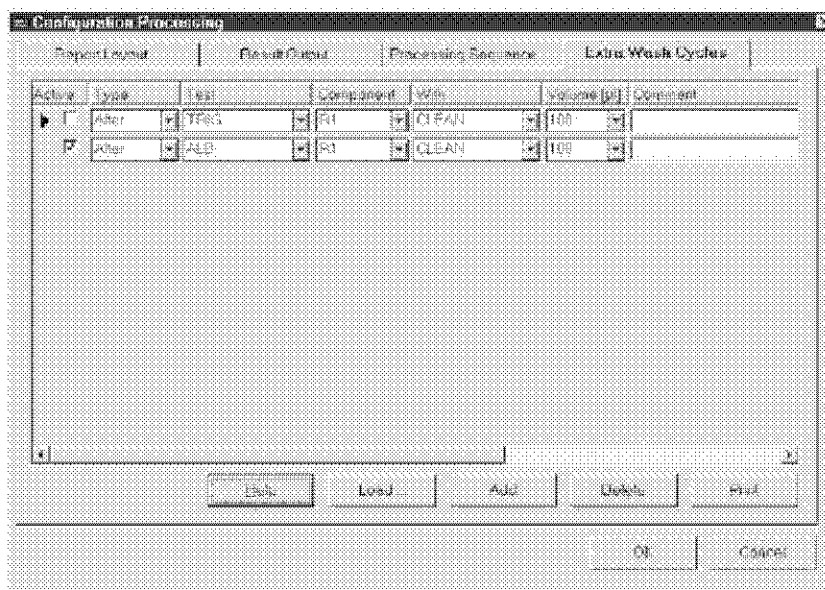
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## Configuration / Processing / Extra Wash Cycles

- 1 Click the Extra Wash Cycles tab in Configuration / Processing.



- 2 Click Load to load the actual Extra Wash Cycle (EWC) table.
- 3 Specify the path from where the wash cycles should be loaded. Default: C:/Roche/Instrument/TAS.
- 4 Select the Extra Wash Cycle file.
- 5 Once the Extra Wash Cycle (EWC) table is loaded, you can switch off an Extra Wash Cycle by clearing the Active check box, provided the test/reagent combination is not in use on the system.
- 6 Click Add to define an additional EWC.
- 7 Define the type, affected test, component, cleaner, and cleaner volume.

The actual Extra Wash Cycle (EWC) settings are shown in "Configuration / Definitions / Tests / Class/Group / Test Sequence" on page 57.



*Whenever new tests are added to the current test list, the Extra Wash Cycle is automatically loaded.*



*Roche strongly recommends that you do not change the predefined Extra Wash Cycle (EWC) settings.*