



Field Safety Notice

Notice Ref No:	< reference number >
Document Date:	15 Nov 2006

PRODUCT AFFECTED:	Immunoglobulin G (Turbidimetric) (IGGT) Tina-quant Gen.2 Albumin (ALBT2)
SYSTEM AFFECTED:	COBAS INTEGRA [®] 700 and 800
MATERIAL NUMBERS:	IGGT cassette, Cat. No. 20766631-322 ALBT2 cassette, Cat. No. 04469658-190
LOT NO (IF APPLICABLE):	All lots
SUMMARY OF ISSUE:	Carry-over from ALBT2 assay to IGGT assay on COBAS INTEGRA[®] 700 and 800
ACTION REQUIRED:	Implementation of an extra wash cycle
CONTACTS:	Technical Services: Country:

Reason for bulletin:

Carry-over from Tina-quant Gen.2 Albumin (ALBT2) assay to Immunoglobulin G (Turbidimetric) (IGGT) assay on COBAS INTEGRA[®] 700 and 800

Dear Customer

We regret to inform you that the R2 reagent of the Tina-quant Gen.2 Albumin assay (ALBT2; Id. No. 04469658-190) shows a carry over effect on the Immunoglobulin G (Turbidimetric) (IGGT, IId. No. 20766631-322) assay. Serum samples as well as cerebrospinal fluid samples are affected. For CSF samples the increase of the signal can be up to around 8 mg/L and for serum it could be in the range of 0.6 to 1.8 g/L. Detailed experiments showed that the problem is related to an interaction of the anti-Albumin antibody with the IgG/anti-IgG complex within the IGGT assay. Other assays are not affected.

The problem occurs only on the COBAS INTEGRA[®] 700 and 800 systems. On the COBAS INTEGRA[®] 400 the effect was not seen due to a different pipetting sequence, which allows a constant wash of the needle between pipetting.

Therefore we have to advise you to perform an extra wash cycle whenever using both cassettes (ALBT2 and IGGT) on COBAS INTEGRA[®] 700 and 800 systems.

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

Action required:

The definition and configuration of extra wash cycles is described in detail **Extra Wash Cycles** in Chapter 8, Software Reference, User Manual (COBAS INTEGRA 700 analyzer, page 127-128); and in Part G, Configuration, User Manual (COBAS INTEGRA 800 analyzer, page 377-378). For your convenience we have attached the respective instructions of the User Manual to this Field Safety Notice.

The Reagent Carry-Over list in the Method Manual will be updated respectively.

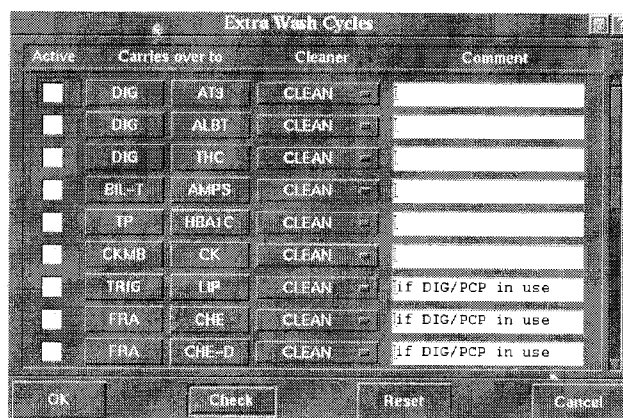
Cassette combination in use		Extra Wash Cycle Configuration
ALBT2	IGGT	ALBT2/IGGT/CLEAN

We apologize for any inconvenience this problem may cause you.

Kind regards,

Processing > Extra Wash Cycles

Call up Configuration > Processing > Extra Wash Cycles



Function Use *Extra Wash Cycles* to define a wash cycle between different tests.

Information For certain combinations, some tests may be affected by reagent carry-over when they are run sequentially. This can be avoided by performing a *Cleaner Test* between tests. Cleaner tests can be selected only if they have been specified beforehand.

► To enter a test number for a cleaner



- 1 Choose Definitions > Tests in Configuration work area.
- 2 Select a cleaner.
- 3 Choose Modify > Identification.
- 4 Enter the test number for the cleaner.

Only the activated cleaner tests can be used.

If the cleaning cassette for the cleaner test selected is empty or not available, the tests requiring this cassette are disabled.


Operation Wash cycles can be switched on and off in the *Active* column.

► To activate a wash cycle

- 1 Specify the cassettes between which carry-over occurs and where a cleaner test is required.
- 2 Click  in column one to select the cassette after which you would like to perform a wash cycle. Click on the test.
- 3 Click  in column two to select the cassette before which you would like to perform a wash cycle. Click on the test.
- 4 Restart the software to apply your changes.

To always clean before or after a specific test use the *All* function. *All* is an option in the *Cassette Selection*.

► **To activate the *All* selection**

- 1 Click  to obtain the *Cassette Selection*. Click *All*.
- 2 When *All* appears in the first column, a wash cycle is performed prior to each pipetting from the cassette designated in column two.
- 3 When *All* appears in the second column, a wash cycle is performed prior to each pipetting from the cassette designated in column one.
- 4 Select the cleaner test in *Cleaner* column.
- 5 Enter your own notes under *Comment*.
- 6 Restart the software to apply your changes.

Input fields

Cleaner


Select field; select the cleaner test required.

Comment

Input field for 20 alphanumeric characters


Accessible windows

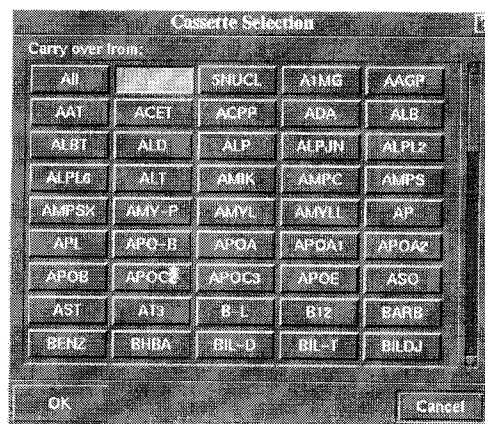
Cassette Selection

Click  with the select mouse button.

Cassette Selection

Call up


Configuration > Processing > Extra Wash Cycles > Click 



Function Use *Cassette Selection* to define the cassettes between which a cleaner test should be carried out.

Information The title of this window varies, depending on whether the first or second push button in the window *Extra Wash Cycles* was clicked *Carry over from* or *Carry over to* appears.


Operation Click on a cassette to select it.

 in *Extra Wash Cycles* window means that no cassette has been selected.

Processing menu

The Processing menu lists all settings for customizing the automatic result handling, the result output, the Extra Wash Cycles, and the workflow adaptation.

From time to time you may need to adapt the Result Handling Table or the Extra Wash Cycle settings to new or changed COBAS INTEGRA reagents.

 For more information about the individual configuration functions click ? in the window.

- | | |
|------------------------------|--|
| <i>Result Handling Table</i> | <ul style="list-style-type: none"> • Define automatic result handling for flagged and unflagged calibration, control, and sample results. |
| <i>Result-Output Mode</i> | <ul style="list-style-type: none"> • Customize the printout mode for results and messages. • Enable the data transmission to the host computer and select the data mode. |
| <i>Sequence</i> | <ul style="list-style-type: none"> • Define the processing sequence for tests performed out of a sample. |
| <i>Extra Wash Cycles</i> | <ul style="list-style-type: none"> • Define Extra Wash Cycles for certain cassette combinations on board. |
| <i>Workflow adaptation</i> | <ul style="list-style-type: none"> • Define the number of STAT slots on the carousel for RD 5 STAT racks. • Define the rack delay time for RD 5 racks. • Define the RD 5 rack release mode. • Enable or disable the Automatic Output Tray Printout function. |

Modifying the automatic result handling

The automatic processing of flagged and unflagged calibration, control, and sample results is defined in the Result Handling Table. For each flag up to three flag actions can be defined. Flag actions include rerun, postdilution, postconcentration, accept, or automatic test disabling.

► To modify the result handling

- 1** Open the Configuration work area.
- 2** Choose Processing > Result Handling Table.
The Result Handling Table window is displayed.
- 3** Select Automatic Result Handling.
- 4** Select Cal, QC, or Sample for which automatic result handling should be carried out.
- 5** Select a flag for automatic result handling in the list.
- 6** Choose the Flag Actions for the selected flag.
 - None: no automatic action follows.
 - Repeat: the measurement is rerun automatically as default.
 - Cal. repeat: the calibration is repeated automatically.
 - Postaction 1: the measurement is rerun automatically with the treatment defined for postaction 1 for this test.
 - Postaction 2: the measurement is rerun automatically with the treatment defined for postaction 2 for this test.

- Disable test: the test is automatically disabled. No other requests for this test can be processed.
- Accept: the result is accepted automatically.

7 Click OK to save the new settings.



Definitions of postaction 1 and 2 are done in the Configuration work area in the menu Definitions > Tests > Modify > Laboratory.

The settings defined in the Result Handling Table can be individually overruled by the test specific result handling defined in the Configuration work area in the menu Definitions > Tests > Modify > Result Handling.

Set all flags to Accept if the reruns are managed by the host.

Viewing Extra Wash Cycle definitions

The instrument is delivered with a default setting for Extra Wash Cycles.

► To view Extra Wash Cycle definitions

- 1 Open the Configuration work area.
- 2 Choose Processing > Extra Wash Cycles.
- 3 View the Extra Wash Cycles and the comments.
- 4 Click OK to close the window.




You cannot change settings for cleaner.

Click the Active check box to activate or deactivate the Extra Wash Cycles.

Definitions menu

The Definitions menu contains all the definitions for tests, calibrators, controls, diluents, and cassettes. Each definition can be modified to meet your laboratory requirements. This area of the Configuration work area is the part, where you do most of the changes.

 For more information about the individual configuration functions click ? in the window.

Tests

The Tests window lists all definitions for tests, profiles, and ratios that are available on the system.

A test definition contains all the information the system needs in order to run a test. You can customize selected parameters of the definition to your laboratory environment. Select an entry in the list and choose a menu command from the Tests window to modify a test definition.

- | | |
|-----------------------|--|
| <i>Identification</i> | <ul style="list-style-type: none"> • Define test number, short name, and test name, and see part number and version of the test definition. |
| <i>General</i> | <ul style="list-style-type: none"> • Define default sample type and calibration sequence. |