

Urgent Field Safety Notice

Notice Ref No:	<i>FSN_RPD_2014_02</i>
Document Date:	March xx, 2014
Type of Action	Field Corrective Action

SYSTEMS AFFECTED:	cobas c 502 module
DEVICE:	cobas c pack MULTI, cobas c pack for CARB3 and GENTQ (US only)
SUMMARY OF ISSUES:	<p>Since the Integrated Cassette Volume Check (ICVC) was not activated in the Reagent Container (REC) files on cobas c 502 modules for assays requiring manual preparation, an erroneous filling volume or interchanging R1 and R2 into the cobas c pack would not be detected by the analyzer.</p>
ACTION REQUIRED:	<p>The filling instructions indicated in the package insert have to be followed exactly. Please ensure that the correct and current revision is being used.</p> <p>Ensure that the cobas link and cobas 8000 data manager are up-to-date, so that the current REC file versions with (ICVC setting "ON") are available for the analyzer.</p>
CONTACTS:	<p>Technical Services: xxx Country: xxx</p>

Reason for notice:

Due to an in-house labeling software limitation, the ICVC “ON” settings are not correctly encoded in the REC files released to the market so far, and in consequence no ICVC was performed on **cobas c 502** modules.

Affected tests: Only those requiring a manual reagent handling (see table 1)

Assay Kit	GMMI no.	Manufacturer	Updated Lots with ICVC ON in REC file version 2	Expiry Date
ACP2	04375351 190	Roche Diagnostics	660693 673716 691766 697305...**	2014-02 2014-08 2014-08 2015-09
CHE	11877763 216	Roche Diagnostics	669364 685504 689138 696860...**	2014-09 2015-05 2015-09 2016-03
DBILI	04924495 190	Roche Diagnostics	666725 672105 680676 685887 691135 697505	2014-02 2014-06 2014-10 2015-01 2015-05 tbd
D-BIL	11555413 216	Roche Diagnostics	660412	2014-07
GLDH3	11929992 216	Roche Diagnostics	674719 684340 689643 692834	2014-03 2014-08 2014-08 2015-01
HBDH	11876937 216	Roche Diagnostics	684997 687135 694052	2014-05 2014-07 2014-12
TRIGB	11877771 216	Roche Diagnostics	685740 695385	2014-04 2014-11
A1MG2	03576116 190	Roche Diagnostics	669683 675475 688017	2014-06 2014-11 2015-04
B2MG	11660551 216	Roche Diagnostics	683969 686536 688791 691820 693904 695930	2014-03 2014-05 2014-06 2014-09 2014-10 2014-12
KAPP2	11820176 316	Roche Diagnostics	670559 686248 695709	2014-04 2014-12 2015-08
LAMB2	11820184 316	Roche Diagnostics	670566 684595 693844	2014-05 2014-12 2015-06

Assay Kit	GMMI no.	Manufacturer	Updated Lots with ICVC ON in REC file version 2	Expiry Date
CARB3	04874625 190	Roche Diagnostics	676413 685351 689905 692916 697098	2014-04 2014-04 2015-01 2015-01 2015-05
DRI MM (EDDP)	05178576 190	Thermo Fisher	600262 604205	2014-04 2014-12
DRI OXY	05179459 190	Thermo Fisher	598516 599795 601541 604471	2014-04 2014-10 2015-01 2015-09
GENTQ	05889332 190	Thermo Fisher	601693 603976 604047 604725	2014-03 2014-03 2014-05 2014-10
KAP	05000238 190	Binding Site	660595 669126 327896 330821 337341 341666	2014-03 2014-07 2015-01 2015-04 2015-11 2016-02
LAM	05000327 190	Binding Site	660596 669127 327897 330822 337342 341668	2014-03 2014-07 2015-01 2015-04 2015-11 2016-02
TPLA	04955137 190	Sekisui	628286 628292 628298 681727 681733 681824 681926 681932 681938...**	2014-03 2014-05 2014-07 2014-09 2014-11 2015-01 2015-04 2015-05 2015-07

** new lot with ICVC activated in REC file ver.1

The following table summarizes the consequences and severity of a zero reagent pipetting for Roche manufactured assays in case of erroneous **cobas c** pack filling:

Assay Kit	GMMI no.	Consequence of zero reagent pipetting
DBILI	04924495 190	<ul style="list-style-type: none"> · sample result = 0, which is valid · sample result is not flagged · calibration fails and is flagged: "SENS" · control result is incorrect
D-BIL	11555413 216	
CARB3	04874625 190	
ACP2	04375351 190	<ul style="list-style-type: none"> · sample result = 0, which is not valid · sample result is not flagged · calibration fails and is flagged: "SENS" · control result is incorrect
CHE	11877763 216	
GLDH3	11929992 216	
HBDH	11876937 216	
TRIGB	11877771 216	
A1MG2	03576116 190	
B2MG	11660551 216	
KAPP2	11820176 316	
LAMB2	11820184 316	

The following table summarizes the consequences and severity of a zero reagent pipetting for assays from other manufacturers in case of erroneous **cobas c** pack filling:

Assay Kit	GMMI no.	Consequence of zero reagent pipetting
MM (EDDP)	05178576 190	<ul style="list-style-type: none"> · sample result = 0, which is valid · sample result is not flagged · calibration fails and is flagged: "SENS" · control result is incorrect
OXY	05179459 190	
TPLA	04955137 190	
KAP	05000238 190	<ul style="list-style-type: none"> · sample result = 0, which is not valid · sample result is not flagged · calibration fails and is flagged: "SENS" · control result is incorrect
LAM	05000237 190	

Action required:

- For **cobas c** 502 customers running these tests, load new cassettes from the concerned lots after the availability of the updated version of the REC files, or provide the most current reagent lots, having ICVC implement already in REC file (see table 1)
- For KAPP2, LAMB2 and HBDH2, switch to ready-to-use **cobas c** packs
- Ensure that the cobas link and cobas 8000 data manager are up-to-date, so that the updated REC file versions are available for the analyser.

- The REC files themselves are nowhere displayed in the User Interface, and therefore the version in use cannot be checked by the operator. However, following workaround is available:
The ICVC pipetting itself can be observed visually during the reagent registration process (after piercing the new cassette and before automatic placement on reagent disc, the reagent probe will move into each reagent compartment).
- Offline systems not connected to cobas e-Library have to be updated manually with the latest e-Library CD (created after February 28, 2014 i.e. after complete availability of updated REC files, see above) in order to ensure availability of the updated REC file version.

We apologize for any inconvenience this issue may have caused.

The undersign confirms that this notice has been notified to the appropriate
Regulatory Agency
(Closing paragraph)
Signature