

# Urgent Field Safety Notice

<b>Notice Ref No:</b>	<b>FSN_RPD_2012_02</b>
<b>Document Date:</b>	<b>February 15, 2012</b>
<b>Type of Action</b>	<b>Field Corrective Action</b>

<b>SYSTEMS AFFECTED:</b>	<p><b>COBAS INTEGRA<sup>®</sup> 400/ 400 plus</b>  <b>COBAS INTEGRA<sup>®</sup> 800 analyzer</b>  <b>cobas c 311/501/502 analyzer</b></p>
<b>DEVICE::</b>	<p><b>cobas c-pack MULTI</b></p>
<b>SUMMARY OF ISSUES:</b>	<p><b>Since the Integrated Cassette Volume Check (ICVC) is switched off in the barcode label data, an erroneous filling volume of cobas c-pack MULTI (assays requiring manual preparation) would not be detected by the analyzer.</b></p>
<b>ACTION REQUIRED:</b>	<p><b>The filling instructions indicated in the package insert have to be followed exactly. Please ensure that the correct and current revision is being used.</b>  <b>Be aware that the IVCV check setting will be or have been activated via labels on respective products.</b></p>
<b>CONTACTS:</b>	<p><b>Technical Services: xxx</b>  <b>Country: xxx</b></p>

**Reason for notice:**

A UK customer recently reported a false negative TPLA result on **cobas c 501**.

Intensive investigations revealed the following potential reasons:

- Ø The manual filling instructions of the cobas c-pack MULTI were not followed correctly.
- Ø Lower volumes as indicated in the package insert were filled in the cobas c-pack MULTI reagent compartments at the customer site.

∅ As a consequence, the reagent probe will aspirate air causing e.g. a false negative TPLA result on cobas c 501.

∅ The following assays also require manual handling steps using the cobas c pack MULTI with ICVC OFF:

Assay Kit	GMMI no.	Manufacturer	ICVC	Remarks	Available on	
					cobas c 311/501/502	COBAS INTEGRA®
ACP2	04375351 190	Roche Diagnostics	off	quantitative pour over	yes	yes
CHE	11877763 216	Roche Diagnostics	off	quantitative pour over	yes	no
DBILI	04924495 190	Roche Diagnostics	off	quantitative pour over	yes	no
D-BIL	11555413 216	Roche Diagnostics	off	quantitative pour over	yes	no
GLDH3	11929992 216	Roche Diagnostics	off	quantitative pour over	yes	yes
HBDH	11876937 216	Roche Diagnostics	off	quantitative pour over	yes	yes
TRIGB	11877771 216	Roche Diagnostics	off	quantitative pour over	yes	no
A1MG2	03576116 190	Roche Diagnostics	off	quantitative pour over	yes	yes
B2MG	11660551 216	Roche Diagnostics	off	quantitative pour over	yes	no
KAPP2	11820176 316	Roche Diagnostics	off	quantitative pour over	yes	yes
LAMB2	11820184 316	Roche Diagnostics	off	quantitative pour over	yes	yes
CARB3	04874625 190	Roche Diagnostics	off	quantitative pour over	yes	no
MM (EDDP)	05178576 190	Thermo Fisher	off	quantitative pour over	yes	yes
OXY	05179459 190	Thermo Fisher	off	quantitative pour over	yes	yes
TPLA	04955137 190	Sekisui	off	separation of R1 reagent	yes	no
GENTQ	05889332 190	Thermo Fisher	on	--	yes	no
KAP	05000238 190	Binding Site	on	--	yes	yes
LAM	05000327 190	Binding Site	on	--	yes	yes

Please note:

- ∅ For TPLA, the integrated cassette volume check (ICVC) was activated on the label starting with lot no. 628267.
- ∅ On **cobas c 701/702/711** the filling volume is checked by liquid level detection so that erroneous results caused by incorrect filling can be excluded.

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

Assay Kit	GMMI no.		Consequence of zero reagent pipetting
DBILI	04924495	190	<ul style="list-style-type: none"> <li>· sample result = 0, which is valid</li> <li>· sample result is not flagged</li> <li>· calibration fails and is flagged: "SENS"</li> <li>· control result is incorrect</li> </ul>
D-BIL	11555413	216	
CARB3	04874625	190	
ACP2	04375351	190	<ul style="list-style-type: none"> <li>· sample result = 0, which is <b>not</b> valid</li> <li>· sample result is not flagged</li> <li>· calibration fails and is flagged: "SENS"</li> <li>· control result is incorrect</li> </ul>
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 Multi filling:

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

\*Please note:

- Ø For TPLA, the integrated cassette volume check (ICVC) was activated on the label starting with lot no. 628267.

**Action required:**

- The issue can be excluded by following the instructions for use: for manually filled reagents used in combination with cobas c-packs MULTI, the filling instructions indicated in the package insert have to be followed exactly to avoid erroneous results.

- The ICVC check is already activated on the cobas c-pack MULTI label which is included in the TPLA reagent kit GMMI no. 04955137 190. The modified label is available starting with lot no. 628267.
- In order to offer additional safety and convenience for all reagents used in cobas c packs Multi, the ICVC check will be activated on the label of the respective products. We will inform you in due time about the starting lot numbers of the new barcodes.

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