

Urgent Field Safety Notice

Notice Ref No:	<i>FSN SB RPD 2012_09</i>
Document Date:	24-Oct-2012

PRODUCT AFFECTED:	<ALP2, ALT, CO2-L, CREJ2, CRPL3, UREAL>
SYSTEM AFFECTED:	< cobas 8000 modular analyzer series >
MATERIAL NUMBERS:	05166888 190 05850797 190 05446376 190 05168597 190 05172373 190 05171873 190
LOT NO (IF APPLICABLE):	
SUMMARY OF ISSUE:	Patient sample and control recovery on cobas c 701 / cobas c 702 modules
ACTION REQUIRED:	Mandatory download for a new version of the application e-barcode for the affected parameters
CONTACTS:	Technical Services: Country:

Reason for notice:

Mismatch between the reagent probe positioning on **cobas c 701** and **cobas c 702** modules and the aspirated reagent volumes leading to insufficient reagent pipetting under certain conditions (all control unit software versions are affected).

Dear Customer,

We regret to inform you that due to a software bug on the **cobas 8000** modular analyzer series a mismatch between the reagent probe positioning on **cobas c 701** and **cobas c 702** modules and the aspirated reagent volumes may occur.

This may lead to partial air pipetting at the end of the **cobas c** pack large and accordingly the patient samples and controls recovery may be affected.

In order that this happens, the following four conditions must be fulfilled simultaneously:

- Reagents are diluted with system water as part of the application.
- The reagent pipettor aspirates reagent volumes at the upper limit of the volume specification.
- A certain combination of tests per **cobas c** pack large and pipetting volume.
- There is only one initial registration of a reagent **cobas c** pack large, i.e. the **cobas c** pack large is used continuously without re-registration (which typically occurs every morning during maintenance).

Investigations have revealed that the following parameters are affected:

CRPL3, ALP2, ALT, CO2-L, CREJ2 and UREAL

We are working with the highest priority to release a new software version to fix that issue.

Meanwhile and until the new software version is available, we have updated the application e-barcode for the affected parameters, which reduce the available number of tests to the level shown in the table below. The filling volume for those **cobas c** pack large remains unchanged. All other settings remain the same. The revised applications can be loaded into the **cobas c 701** and **cobas c 702** modules via the **cobas e-library**. The revised application will cause the analyzer to switch to a new pack once the reduced number of tests has been pipetted out of the pack.

The table below shows the number of tests per **cobas c** pack large which can be safely pipetted without risk of insufficient reagent volume:

Name	ID-No.	SPV	Code No.	Current no. of Tests	Reduced no. of tests
ALP2	05166888	190	0567603	1050	750
ALT	05850797	190	0575010	1100	800
CO2-L	05446376	190	0567255	2050	1460
CREJ2	05168597	190	0569282	3000	1780
CRPL3	05172373	190	0569932	500	370
UREAL	05171873	190	0563039	1900	1350

The following table shows the updated version number:

Test name /ACN	Version with full number of tests	Updated version with reduced number of tests
ALP2L: 8683	0602	0803
ALTL: 8685	0604	0705
CO2-L: 8156	0504	0605
SCO2L: 8763	0503	0604
CREJ2: 8690	0904	1005
CRJ2U: 8691	0803	1004
SCRE2: 8773	0904	1005
SCR2U: 8774	0803	1004
CRPL3: 8210	0704	0805
UREAL: 8418	0603	0704
U-BUN: 8421	0603	0704
URELU: 8417	0303	0404
UBUNU: 8428	0403	0504
SUREA: 8419	0303	0404
SUBUN: 8427	0303	0404
SUREU: 8420	0203	0304
SBUNU: 8429	0203	0304

Actions required:

Meanwhile and until the release of the new software version fixing that issue please download via the cobas e-library the new version of the application e-barcode for the affected parameters.

We apologize for any inconvenience caused by that issue.

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