

Urgent Field Safety Notice

Notice Ref No:	<i>FSN_SB_RPD_2013_04</i>
Document Date:	dd-mmm-2013

PRODUCT AFFECTED:	<control unit software>
SYSTEM AFFECTED:	<cobas 8000 modular analyzer series configurations which include cobas e 602 module>
MATERIAL NUMBERS:	See list below
LOT NO (IF APPLICABLE):	n/a
SUMMARY OF ISSUE:	An incorrect diluent may be used under certain circumstances when using automatic dilution on cobas e 602 module
ACTION REQUIRED:	Please follow the described workaround
CONTACTS:	Technical Services: Country:

Products affected:

cobas 8000 modular analyzer series, control unit software versions 02-02 / 03-01 / 03-02 / 03-03 / 03-04:

SW version	GMMI No:
02-02	05846480001
03-01	06323600001
03-02	06450873001
03-03	06733794001
03-04	06912435001

Reason for notice:

To inform about a software bug leading to the possibility that an incorrect diluent may be used under certain circumstances when using automatic dilution on **cobas e 602**

module.

Dear Customer,

We regret to inform you that due to a software bug on the **cobas** 8000 modular analyzer series an incorrect diluent may be used under certain circumstances when using automatic dilution on **cobas e** 602 module.

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

- More than a total of 2000 reagents kits or diluents had been registered on the **cobas e** 602 modules within one configuration.
- Two or more different diluent types are available on board in parallel (e.g. Diluent Universal and Diluent MultiAssay).
- A different type of diluent (e.g. Diluent Universal) had been previously registered in the database with the identical key information as the current diluent of another type (e.g. Diluent MultiAssay). As an example, Diluent Universal had been registered with a specific key information (e.g. "55": 1-2000 are possible) and 2000 reagent kits later (once the 2000 key information had been exceeded in the data base) the specific key information of "55" had been assigned to Diluent MultiAssay.

The root cause has been clearly identified and the problem will be fixed in the upcoming control unit software version 04-01.

Actions required:

Meanwhile, please follow the following workaround whenever a new diluent reagent pack for the cobas e 602 module is placed on board in case that more than one diluent type is used:

Check the assays listed as suitable for the newly placed diluent pack in Overview / Reagent Overview / Detail (see attachment cobas e 602 screen.pptx).

Each diluent package contains a note that informs which assay can be (auto-) diluted with the respective diluent (see attachment note diluent universal.pdf and diluent multiassay.pdf).

Compare the assays listed in the note and in the screen mentioned above.

If the assays listed in the note and on the screen match completely, there is no problem and no further action required.

If the assays listed in the note and on the screen differ (e.g. if TSH is listed for Diluent Universal instead of Diluent MultiAssay), following actions are required:

- Replace the diluent pack (which has more assays listed in the screen than in the note) by another diluent pack of the same lot. Please make sure afterwards

that the assays listed in the note and on the screen matches.

- If the assays listed in the note and on the screen still don't match, it would be then necessary to replace this diluent pack by a diluent pack of a different lot.
- If no other diluent lot is available then in that case only one type of diluent pack (e.g. only Diluent Universal) must be placed in the reagent disk of the cobas e 602 module. As a consequence, manual dilution is required for all assays using a different diluent type.

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

Attachments:

<Supporting data>

Remote Control

Stand By

bmserv

08/03/2013 17:25



Workplace

Reagent

Calibration

QC

Utility

Overview

Reagent Overview (AU1)

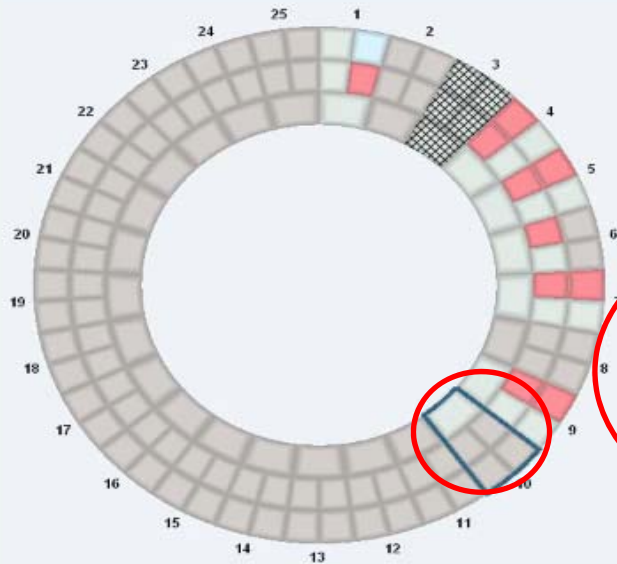
Contents

R. P.	Active	Preparation	Warning	Caution
Cal.	Valid		Requested	Failed
QC	Valid		Requested	Failed

Detail

Position	10
Type	DIL
Name	Dil Uni
R. Pack Lot ID	16331300
R. Pack Seq. No.	047627
First Registration Date and Time	2013-02-27 09:14
Exp. Date	2013-05 (75)
Status	
Remaining Volume	4 ml

Reagent



- Test Name
- CMVIGG
- CMVIGM
- PRL
- CORT
- F-BHCG
- CK-MB



Close

Inventory Update

Close



Diluent MultiAssay

Elecsys



LOT 172413

 2015-06

REF 03609987 190

Components Komponenten Constituant Componente Componente Komponenter Komponenter Složka Zložky Składniki Alkotóelemek Συστατικά	Method Methode Méthode Método Metodo Metod Metode Metoda Metóda Metoda Módszer Μέθοδος			
		Elecsys 2010 and cobas e 411	MODULAR ANALYTICS E170	cobas e 601 and cobas e 602
CK-MB	Elecsys CK-MB 11821598	-	•	•
CK-MB	Elecsys CK-MB 05894808	•	•	•
CKMBSTAT	Elecsys CK-MB STAT 11731432	-	-	•
CKMBSTAT	Elecsys CK-MB STAT 05957648	•	-	•
CPEPTID	Elecsys C-Peptide 03184897	•	•	•
E2	Elecsys Estradiol II 03000079	•	•	•
hCT	Elecsys Calcitonin 06445853	•	•	•
HE4	Elecsys HE4 05950929	•	•	•
IL6	Elecsys IL-6 05109442	•	•	•
SHBG	Elecsys SHBG 03052001	•	•	•
TG II	Elecsys Tg II 06445896	•	•	•
TNT-HS	Elecsys Troponin T hs 05092744	•	•	•
TNT-HSST	Elecsys Troponin T hs STAT 05092728	•	-	•
TN-I	Elecsys Troponin I 05094810	-	•	•



Diluent MultiAssay

Elecsys

cobas®

LOT 172413 2015-06

TNISTAT	Elecsys Troponin I STAT 05094798	.	-	.
TSH	Elecsys TSH 11731459	.	.	.

- Dilution possible / Verdünnung möglich / Dilution possible / Se puede diluir / Diluizione possibile / É possível diluir / Spädning möjlig / Fortynding mulig / Ředění možné / je možné riediť / Rozcieńczenie możliwe / Hígítás lehetséges / Είναι δυνατή η αραίωση
- Dilution not possible / Verdünnung nicht möglich / Dilution impossible / No se puede diluir / Diluizione impossibile / Não é possível diluir / Spädning ej möjlig / Fortynding ikke mulig / Ředění není možné / nie je možné riediť / Rozcieńczenie niemożliwe / Hígítás nem lehetséges / Δεν είναι δυνατή η αραίωση

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US Customer Technical Support 1-800-428-2336



Diluent Universal

Elecsys

cobas®

LOT 171219

2014-10

REF 03183971 122

Components Komponenten Constituant Componente Componente Komponenter Komponenter Složka Zložky Składniki Alkotóelemek Συστατικά	Method Methode Méthode Método Metodo Método Metod Métode Metoda Metóda Metoda Módszer Μέθοδος	Elecsys 2010	cobas e 411	MODULAR ANALYTICS E170	cobas e 601	cobas e 602
PRL	Elecsys Prolactin II, 03203093	•	•	•	•	•
CORT	Elecsys Cortisol, 11875116	•	•	•	•	•
HCGSTAT	Elecsys HCG STAT, 03300811	•	•	–	•	•
TP1NP	Elecsys total P1NP, 03141071	•	•	•	•	•
TNTSTAT	Elecsys Troponin T STAT, 04660307	•	•	–	•	•
CKMBSTAT	Elecsys CK-MB STAT, 11731432	•	•	–	•	•
CKMBSTAT	Elecsys CK-MB STAT, 05957648	–	–	–	•	•
TN-T	Elecsys Troponin T, 04491815	•	•	•	•	•
CK-MB	Elecsys CK-MB, 11821598	•	•	•	•	•
CK-MB	Elecsys CK-MB, 05894808	–	–	•	•	•
MYO	Elecsys Myoglobin, 12178214	•	•	•	•	•
MYO-STAT	Elecsys Myoglobin STAT, 11820788	•	•	–	•	•
DIGIT	Elecsys Digitoxin, 03002659	•	•	•	•	•
PRO-BNP	Elecsys proBNP II, 04842464	•	•	•	•	•
PROBNPST	Elecsys proBNP II STAT, 05390109	–	–	–	•	•
CEA	Elecsys CEA, 11731629	•	•	•	•	–
CEA	Elecsys CEA, 04491777	–	–	•	•	•
AFP	Elecsys AFP, 04481798	•	•	•	•	–
AFP	Elecsys AFP, 04491742	–	–	•	•	•
TPSA	Elecsys total PSA, 04641655	•	•	•	•	–
TPSA	Elecsys total PSA, 04491734	–	–	•	•	•
CA15-3	Elecsys CA 15-3 II, 03045838	•	•	•	•	•
CA125	Elecsys CA 125 II, 11776223	•	•	•	•	•



REF 03183971 122

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CA19-9	Elecsys CA 19-9, 11776193	•	•	•	•	•
CA72-4	Elecsys CA 72-4, 11776258	•	•	•	•	•
CYFRA	Elecsys CYFRA 21-1, 11820966	•	•	•	•	•
FERR	Elecsys Ferritin, 03737551	•	•	•	•	–
FERR	Elecsys Ferritin, 04491785	•	•	•	•	•
AHBS	Elecsys Anti-HBs, 11820524	•	•	•	•	•
A-HBCIGM	Elecsys Anti-HBc IgM, 11820567	•	•	•	•	•
A-HAVIGM	Elecsys Anti-HAV IgM, 11820591	•	•	•	•	•
TOXIGG	Elecsys Toxo IgG, 04618815	•	•	•	•	•
TOXIGM	Elecsys Toxo IgM, 04618858	•	•	•	•	•
RUBIGG	Elecsys Rubella IgG, 04618793	•	•	•	•	•
RUBIGM	Elecsys Rubella IgM, 04618831	•	•	•	•	•
DIGO	Elecsys Digoxin, 11820796	•	•	•	•	•
IGE	Elecsys IgE II, 04827031	•	•	•	•	•
OSTEOC	Elecsys N-MID Osteocalcin, 12149133	•	•	•	•	•
TG	Elecsys Tg, 05118921	•	•	•	•	•
HCG-BETA	Elecsys HCG+β, 03271749	•	•	•	•	•
F-BHCG	Elecsys free βhCG, 04854071	•	•	•	•	•
PAPP-A	Elecsys PAPP-A, 04854098	•	•	•	•	•
CMVIGG	Elecsys CMV IgG, 04784596	•	•	•	•	•
CMVIGM	Elecsys CMV IgM, 04784618	•	•	•	•	•
PTH 1-84	Elecsys PTH (1-84), 05608546	•	•	•	•	•

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Diluent Universal

Elecsys

cobas[®]

LOT 171219

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