

Ö	Immediate Action Required
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	Information Only



URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: c502FSN cobas c pack multi PB 2014_020

Document Date: 18/03/2014

Type of Action: Field Corrective Action

Product Affected: Cobas c pack multi

System Affected: cobas c 502

Summary of Issue: 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 analyser.

Details of Affected

Devices:

Material No: Refer to Table below.

Lot: No: Refer to Table below.

Reason for Notice: Due to an in-house labeling software limitation, the ICVC (Integrated Cassette Volume Check) 'ON' settings are not correctly encoded in the REC (Reagent container files) files released to the market so far, and in consequence no ICVC was performed on **cobas c** 502 modules.

The affected tests are only those requiring a manual reagent handling step (see table below)

Assay Kit	Catalogue Number	Manufacturer	Updated Lots with ICVC On in REC file version 2	Expiry Date

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

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CHE	11877763216	Roche Diagnostics	669364 685504 689138 696860**	2014-09 2015-05 2015-09 2016-03
GLDH3	11929992216	Roche Diagnostics	674719 684340 689643 692834	2014-03 2014-08 2014-08 2015-01
HBDH	11876937216	Roche Diagnostics	684997 687135 694052	2014-05 2014-07 2014-12
TRIGB	11877771216	Roche Diagnostics	685740 695385	2014-04 2014-11
A1MG2	03576116190	Roche Diagnostics	669683 675475 688017	2014-06 2014-11 2014-04
B2MG	11660551216	Roche Diagnostics	683969 686536 688791 691820 693904 695930	2014-03 2014-05 2014-06 2014-09 2014-10 2014-12
KAPP2	11820176316	Roche Diagnostics	670559 686248 695709	2014-04 2014-12 2015-08
LAMB2	11820184316	Roche Diagnostics	670566 684595 693844	2014-05 2014-12 2015-06
DRI	05178576190	Thermo Fisher	600262	2014-04

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MM (EDDP)			604205	2014-12
DRI OXY	05179459190	Thermo Fisher	598516 599795 601541 604471	2014-04 2014-10 2015-01 2015-09
TPLA	04955137190	Sekisui	628286 628292 628298 681727 681733 681824 681926 681932 681938**	2014-03 2014-05 2014-07 2014-09 2014-11 2015-01 2014-04 2015-05 2015-07

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

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

Assay Kit	Catalogue number	Consequence of zero reagent pipetting
CHE	11877763216	<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.
GLDH3	11929992216	
HBDH	11876937216	
TRIGB	11877771216	
A1MG2	03576116190	
B2MG	11660551216	
KAPP2	11820176316	
LAMB2	11820184316	

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

Assay Kit	Catalogue number	Consequence of zero reagent pipetting
MM (EDDP) OXY TPLA	05178576190 05179459190 04955137190	<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

Action Required:

The filling instructions indicated in the package insert have to be followed exactly. Please ensure that the correct and current revision is being used.

Ensure that the cobas link and cobas 8000 data manager are connected so that the updated REC (Reagent container files) file versions are available for the analyser. The REC files are not displayed at the User interface therefore please ensure that the ICVC (Integrated Cassette Volume Check) pipetting itself is observed visually during the reagent registration process (after piercing the new cassette and before automatic placement on the reagent disk, the reagent probe will move into each reagent compartment).

For **cobas c** 502 customers running these tests, load new cassettes from the lot numbers listed above.

Please complete the faxback and return by no later than 26/03/2014.

We apologise for any inconvenience this issue may have caused.

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This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Attachments: Fax back

This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Irish Medicines Board (IMB), and other International Regulatory Agencies.

**** Please bring this notice to the attention of all personnel in your hospital/ Health Care facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this letter to them. ****

**If you require any further information please contact our
Professional Services Department / Technical Support Hotline on:
UK: 0808 100 19 20
Ireland : 1800 40 9 564**

A copy of this notice can also be found on www.cobas-roche.co.uk

To enable Roche Diagnostics to fulfil it's vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.

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