Urgent Field Safety Notice

FSN-RPD-2015-006

RPD / ClinChem fully automated
Version 2
10-Mar-2015

Homocysteine under-recovery in EDTA samples

Product Name	HCYS
Product Description	Homocysteine enzymatic assay
GMMI / Part No **Device Identifier**	05 385 415 190 HCYS (**cobas c**, COBAS INTEGRA®) 06 542 921 190 HCYS (**cobas c** 701, 702) 05 385 377 190 HCYS (MODULAR <P>)
Production Identifier **(Lot No./Serial No.)**	05 385 415 190 Lot No.: 69781101 06 542 921 190 Lot No.: 69781401 05 385 377 190 Lot No.: 69780301
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Customers complained about a 20% decrease in control levels when using non-Roche controls (e.g. ThermoFisher LiqImmune) with Homocysteine reagent lot 697811 on **cobas c** 501. After changing to lot 604303, the controls were within range. The comparison of patient samples with reagent lot 697811 vs 604303 showed a bias of up to 54%. EDTA plasma samples were used. This negative bias could, in the worst case, lead to inaccurately low Homocysteine results. However, it is unlikely that inaccurately low Homocysteine results would lead to an immediate adverse event, since it has been demonstrated that Homocysteine is a predictor of *long-term* (late cardiac events), rather than short-term cardiovascular risk.

Insufficiency of Mg^{2+} in R1 and R2 was identified as the root cause. Since $MgCl_2$ is hygroscopic, the content of the container was absorbing water. Consequently, an insufficient amount of Mg^{2+} was added to the reagents despite the correct weight of $MgCl_2$ salt. Mg^{2+} is necessary for enzyme activity, reagent stability and the practicability of EDTA plasma as sample type. At the time of lot release, the amount of Mg^{2+} added to the reagent was within specification for serum and EDTA samples. As the reagent neared the end of its shelf life, the sample bias became evident with EDTA samples where Mg^{2+} in the reagent was more easily chelated from the enzymes.

Homocysteine under-recovery in EDTA samples

Actions taken by Roche Diagnostics

- Root cause was already identified
- Corrective and Preventive Action has been initiated
- Overall good performance for all forthcoming lots is ensured until the end of shelf life

Actions to be taken by the customer/user

- Customers must stop using the affected product, discard it locally and switch to unaffected subsequent lots (see table below) of **HCYS**:

Analyzer module	Material No.	Affected lots	Exp. Date	Subsequent lots	Exp. Date
Modular <P>	05 385 377 190	69780301	30 Apr 2015	60716101	31 Jan 2016
cobas c 501 **cobas** c 502 **cobas** c 311 COBAS INTEGRA 400 plus COBAS INTEGRA 800	05 385 415 190	69781101	30 Apr 2015	60716801	31 Jan 2016
cobas c 701 **cobas c** 702	06 542 921 190	69781401	30 Apr 2015	60717101	31 Jan 2016

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Sincerely,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com