Ö	**Immediate Action Required**
	Action Required
	Information Only

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: CCFSN_01_15 Homocysteine SBN-RPD-2015-006
Document Date: 13/03/2015
Type of Action: Field Corrective Action

Product Affected:	**HCYS – Homocysteine Enzymatic Assay**
System Affected:	**COBAS Integra® systems,** **MODULAR *ANALYTICS* <P>** **cobas c** 311 **cobas c** 501 **and cobas c** 502 **cobas c** 701 **and cobas c** 702
Summary of Issue:	**Homocysteine under-recovery in EDTA samples.**

Details of Affected Devices:	
Material No:	05385415190 06542921190 05385377190
Lot: No:	697811 697814 697803

Reason for Notice:	Customers complained about a 20% decrease in control levels when using non-Roche controls (for example ThermoFisher LiqImmune) with Homocysteine reagent lot number 697811 on the **cobas c** 501. After changing to reagent lot number 604303, the controls recovered within the specified range. The comparison of patient samples with reagent lot number 697811 versus 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

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that Homocysteine is a predictor of long-term (late cardiac events), rather than short term cardiovascular risk.

The insufficiency of Mg^{2+} in the R1 and R2 reagent has been 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 a 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.

Action Required:

Actions taken by Roche Diagnostics

- The root cause has already been identified.
- Corrective and Preventative Action has been initiated.
- Overall good performance for all forthcoming lot numbers is ensured until the end of shelf life.

Actions to be taken by the Customer

- Customers must stop using the affected product, please discard affected stock locally.
- Customers with affected stock should contact Technical Services to arrange replacement.
- Please complete the attached Fax back and return by no later than the 26th March.

We apologise for any inconvenience caused by this issue.

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: **CCFSN_01_15 Homocysteine SBN-RPD-2015-006 Fax back.**

This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

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** 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 its 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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