

Urgent Field Safety Notice

Notice Ref No:	FSN_RPD_2014_04
Document Date:	14-Apr-2014
Type of Action	Field Corrective Action

SYSTEMS AFFECTED:	MODULAR ANALYTICS <P/D>
Product Name:	CA2
Product Description:	Calcium Gen.2
MATERIAL NUMBERS:	05 061 431 190 (Calcium Gen.2 Mod P/D R1) 05 061 458 190 (Calcium Gen.2 Mod P/D R2) 05 061 466 190 (Calcium Gen.2 Mod D R1) 05 061 474 190 (Calcium Gen.2 Mod D R2)
SUMMARY OF ISSUES:	<p>The performance of Calcium Gen.2 (CA2) on certain Modular analyzers is not accepted by several customers although the performance on Roche internal analyzers is within specification.</p>
ACTION REQUIRED:	<p>Please contact your local Roche affiliate in order to check the maintenance status of the analyzer through Roche service engineer.</p>
CONTACTS:	Technical Services: xxx Country: xxx

Dear valued customer,

We regret to inform you about an issue of Calcium Gen.2 (CA2) on **MODULAR ANALYTICS <P/D>**.

Reason for notice:

In rare cases customers have reported outliers up to 10 % of CA2 that was seen on **Modular ANALYTICS** <P/D>. The issue could not be reproduced by Roche internally as in numerous precision runs, CVs far below 1% were obtained (specification: $CV \leq 2\%$). These investigations clearly demonstrate that there is no reagent related background.

Root cause:

It is assumed that the occurrence of outliers is due to the sensitivity of the assay to the maintenance condition of the **Modular ANALYTICS** <P/D>. On a properly maintained analyzer (i.e. the manufacturer preventative maintenance recommendation is properly followed) the precision of CA2 is within specifications.

Action required:

In case if you encounter significant outliers for CA2 it is recommended to request a Roche service engineer to check the maintenance status of the analyzer.

We apologize for any inconvenience this problem may have caused.

Yours faithfully

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